

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Petcuten Spot-on solution for dogs up to 4 kg

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 0.4 ml contains:

### Active substances:

Imidacloprid:	40.0 mg
Permethrin (40/60):	200.0 mg

### Excipient(s):

Butylhydroxytoluene (E321): 0.4 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-on solution

Clear yellowish to brownish solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs (up to 4 kg)

For dogs more than 4 kg body weight, use the appropriate Petcuten Spot-on solution product (see section 4.9).

### 4.2 Indications for use, specifying the target species

For the treatment and prevention of flea (*Ctenocephalides canis*, *Ctenocephalides felis*) infestation.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

For the treatment of biting lice (*Trichodectes canis*).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks) and against stable flies (*Stomoxys calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

#### **4.3 Contraindications**

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats. (Refer to section 4.5 – Special precautions for use).

#### **4.4 Special warnings for each target species**

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

#### **4.5 Special precautions for use**

##### **i) Special precautions for use in animals**

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under section 4.9. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

**ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

**iii) Other precautions**

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

**4.6 Adverse reactions (frequency and seriousness)**

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### **4.7 Use during pregnancy, lactation or lay**

Can be used during pregnancy and lactation.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

*Dosing Scheme for Petcuten Spot-on:*

Dogs (kg body weight)	Trade name	Volume (ml)	Imidacloprid (mg/kg body weight)	Permethrin (mg/kg body weight)
≤ 4 kg	Petcuten Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
>4 kg ≤ 10 kg	Petcuten Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
>10 kg ≤ 25 kg	Petcuten Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
>25 kg ≤ 40 kg	Petcuten Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
>40 kg ≤ 60 kg	Petcuten Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50- 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten or at least 2 weeks after application, to optimise efficacy of the product.

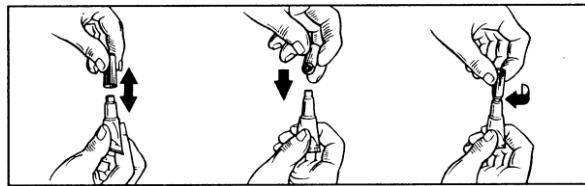
In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

For dermal use only. Apply only to undamaged skin.

#### **Method for administration for short-neck tubes**

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



For dogs 10 kg body weight or less:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



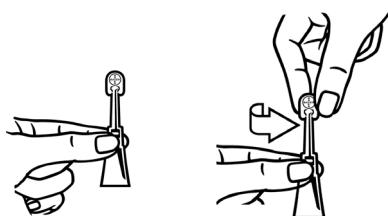
For dogs of more than 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.



#### **Method for administration for long-neck tubes**

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off.



For dogs 10 kg body weight or less:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



For dogs of more than 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.



#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

#### 4.11 Withdrawal period(s)

Not applicable.

### 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic agent,  
ATC vet code: QP53AC54

Petcuten Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

#### 5.1 Pharmacodynamic properties

**Imidacloprid** is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it can be classified as a chloronicotinyl nitroguanidine. Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal. It has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) in insects. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death of the parasite.

**Permethrin** belongs to the type I class of pyrethroid acaricides and insecticides and also acts as repellent. Pyrethroids affect the voltage-gated sodium channels in vertebrates and non-vertebrates. Pyrethroids are so called "open channel blockers" affecting the sodium channel by slowing both the activation and the inactivation properties thus leading to hyperexcitability and death of the parasite.

In the combination of both substances, it has been shown Imidacloprid functions as the activator of arthropod ganglion and therefore increases the efficacy of permethrin.

The product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (e.g. borreliosis, rickettsiosis, ehrlichiosis, leishmaniosis). However, there may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. The product provides repellent (anti-feeding) activity against stable flies thereby assisting in the prevention of fly-bite dermatitis.

The product provides repellent activity (anti-feeding activity) against *Phlebotomus perniciosus* (> 80% for 3 weeks), mosquitoes and ticks. Field data from an endemic area showed that the product indirectly reduces the risk of transmission of *Leishmania infantum* from infected sandflies (*Phlebotomus perniciosus*) for up to 3 weeks, thereby reducing the risk of canine leishmaniosis in treated dogs.

## 5.2 Pharmacokinetic particulars

The product is indicated for dermal administration. Following topical application in dogs, the solution rapidly distributes over the body surface of the animal. Both active substances remain detectable on the skin and hair of the treated animal for 4 weeks.

Acute dermal studies in the rat and target animal, overdose and serum kinetic studies have established that systemic absorption of both active substances after application on intact skin is low, transient and not relevant for the clinical efficacy.

## 5.3 Environmental properties

The product should not be allowed to enter water courses as this may be dangerous for fish and aquatic organisms. For treated dogs, please see section 4.5.

Permethrin containing products are toxic to honey bees.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Butylhydroxytoluene (E321)  
N-Methylpyrrolidone  
Miglyol 812  
Citric acid (E330)

## 6.2 Major incompatibilities

None known.

## 6.3 Shelf life

### Short-neck tube (blistered tubes in pouch):

Shelf-life of product in foil pouch:	5 years.
Shelf life of product after opening foil pouch:	2 years (all pipettes should be used within 2 years after opening the foil pouch or before expiry date on the pipette whichever is shorter).
Shelf-life of the broached pipette:	Not applicable, once opened, the entire content of the pipette has to be applied to the animal's skin.

### Long-neck tube (individually pouched):

Shelf-life of product in foil pouch:	3 years.
Shelf-life of the broached pipette:	Not applicable, once opened, the entire content of the pipette has to be applied to the dog's skin.

#### **6.4. Special precautions for storage**

Do not freeze.

Short-neck tube: After opening the foil pouch store in a dry place at a temperature not above 30°C.

Long-neck tube: After opening the foil pouch the product must be applied to the dog's skin.

#### **6.5 Nature and composition of immediate packaging**

Fill volume: 0.4 ml clear yellowish to brownish, non-aqueous solution per 1 ml pipette (40 mg imidacloprid, 200 mg permethrin).

Type of the container: White polypropylene pipette.

Short-neck tube: White polypropylene cap.

Long-neck tube: Transparent cap.

Material of the secondary packaging: Short-neck tube:

Polychlorotrifluoroethylene PCTFE/PVC heat sealed blister packs in one or more aluminium pouch(es) and a cardboard box.

Long-neck tube:

Single aluminium pouch(es) in a cardboard box.

Package sizes: Packs containing 4 and 6 unit dose pipettes. Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

After use, replace cap on tube. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

### **7. MARKETING AUTHORISATION HOLDER**

*[to be completed nationally]*

### **8. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

### **10. DATE OF REVISION OF THE TEXT**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

### **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****Outer carton, pack size of 4 and 6 pipettes – Product in short-neck tubes****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs up to 4 kg

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 0.4 ml pipette contains:

Active substances: 40 mg imidacloprid, 200 mg permethrin

**3. PHARMACEUTICAL FORM**

Spot-on solution

**4. PACKAGE SIZE**

4 pipettes (4x 0.4 ml)

6 pipettes (6x 0.4 ml)

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

[For cartons: this text for front (only) of carton.]

- Eliminates ticks, fleas and biting lice
- Repels ticks, mosquitos, sand flies, and stable flies
- Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

[For cartons: this text for back (only) of carton]

- Eliminates fleas (treatment and prevention); can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and eliminates ticks; reducing the risk of transmission of CVBD (diseases such as borreliosis, rickettsiosis, and ehrlichiosis).
- Repels mosquitoes and sand flies; reducing the risk of transmission of leishmaniosis.
- Repels stable flies; contributing to the prevention of fly-bite dermatitis.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

**Read the package leaflet before use.**

Keep the foil pouch with the blisters in the outer carton.

[Dog Application –Pictogram (size specific corresponding to the product size]



## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

**Read the package leaflet before use.**

Do not use on puppies of less than 7 weeks of age or 1.5 kg of weight.

**Do not use on cats.**

[Do Not Use on Cats -Pictogram]



## 10. EXPIRY DATE

Expiry/EXP {month/year}

Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.

## 11. SPECIAL STORAGE CONDITIONS

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

*[Prescription status to be completed nationally]*

## 14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:

*[to be completed nationally]*

Distributed by:

*[to be completed nationally]*

**16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**17. MANUFACTURER'S BATCH NUMBER**

Batch No./Lot {number}



[Note: Depending on prevalent pests in CMSs, not all target pest pictograms may be used in every country]

[Figure of pipette, photo of dog]

Other Information:

- Remains effective if the dog becomes wet.
- Provides a larvicidal effect against fleas in the immediate surroundings of the treated dogs
- Can be used on both pregnant and lactating bitches.

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Outer carton, pack size of 4 and 6 pipettes – Product in long-neck tubes**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs up to 4 kg

### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each 0.4 ml pipette contains:

Active substances: 40 mg imidacloprid, 200 mg permethrin

### **3. PHARMACEUTICAL FORM**

Spot-on solution

### **4. PACKAGE SIZE**

4 pipettes (4x 0.4 ml)  
6 pipettes (6x 0.4 ml)

### **5. TARGET SPECIES**

Dogs

### **6. INDICATION(S)**

[For cartons: this text for front (only) of carton.]

- Eliminates ticks, fleas and biting lice
- Repels ticks, mosquitos, sand flies, and stable flies
- Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

[For cartons: this text for back (only) of carton]

- Eliminates fleas (treatment and prevention); can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and eliminates ticks; reducing the risk of transmission of CVBD (diseases such as borreliosis, rickettsiosis, and ehrlichiosis).
- Repels mosquitoes and sand flies; reducing the risk of transmission of leishmaniosis.
- Repels stable flies; contributing to the prevention of fly-bite dermatitis.

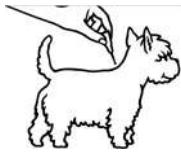
### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

**Read the package leaflet before use.**

Keep the foil pouch(es) in the outer carton.

[Dog Application –Pictogram (size specific corresponding to the product size)]



#### **8. WITHDRAWAL PERIOD(S)**

#### **9. SPECIAL WARNING(S), IF NECESSARY**

**Read the package leaflet before use.**

Do not use on puppies of less than 7 weeks of age or 1.5 kg of weight.

**Do not use on cats.**

[Do Not Use on Cats -Pictogram]



#### **10. EXPIRY DATE**

Expiry/EXP {month/year}

#### **11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

After opening the foil pouch the product must be applied to the dog's skin.

#### **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

#### **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only

*[Prescription status to be completed nationally]*

#### **14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:

*[to be completed nationally]*

Distributed by:

*[to be completed nationally]*

**16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**17. MANUFACTURER'S BATCH NUMBER**

Batch No./Lot {number}



[Note: Depending on prevalent pests in CMSs, not all target pest pictograms may be used in every country]

[Figure of pipette, photo of dog]

Other Information:

- Remains effective if the dog becomes wet.
- Provides a larvicidal effect against fleas in the immediate surroundings of the treated dogs
- Can be used on both pregnant and lactating bitches.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Pipette label – international version (no translation required) – Product in short neck tube and long-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

100 mg/ml imidacloprid(e)  
500 mg/ml permethrin(e)

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

0.4 ml

**4. ROUTE(S) OF ADMINISTRATION****5. WITHDRAWAL PERIOD(S)****6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size]



≤ 4 kg

[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister – international version (no translation required) – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

**4. BATCH NUMBER**

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – size specific corresponding to the product size – to be printed in black and white]



≤ 4 kg

0.4 ml

[Tube-picto]



[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Foil pouch – international version (no further translation required) – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – size specific corresponding to the product size – to be printed in black and white]

**FURTHER INFORMATION**

[Do Not Use on Cats -Pictogram]



Country code	
---	Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.
IT	Utilizzare entro 24 mesi dopo l'apertura della busta di alluminio o prima della data di scadenza (EXP) qualora sia più breve.
NL	Gebruiken binnen 24 maanden na opening van het zakje of vóór

	EXP, het kortste van de twee.
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**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Foil pouch – international version (no further translation required) – Product in long-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

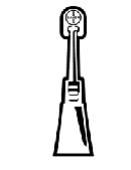
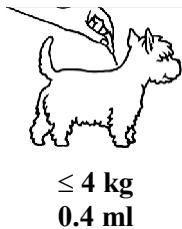
EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – size specific corresponding to the product size – to be printed in black and white]

**FURTHER INFORMATION**

[Do Not Use on Cats -Pictogram]



After opening the foil pouch the product must be applied to the dog's skin.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET [Product in short-neck tubes]**

**Petcuten™ Spot-on solution for Dogs**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder  
[to be completed nationally]

Distributed by:  
[to be completed nationally]

Manufacturer responsible for batch release  
KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs up to 4 kg  
Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg  
Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg  
Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg  
Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg

imidaclorpid, permethrin

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each pipette contains:

	<b>Pipette</b>	<b>Imidaclorpid</b>	<b>Permethrin</b>	<b>N-Methylpyrrolidone</b>	<b>Butylhydroxytoluene (E321)</b>
Petcuten™ Spot-on solution for dogs ≤ 4 kg	0.4 ml	40 mg	200 mg	194 mg	0.4 mg
Petcuten™ Spot-on solution for dogs > 4 ≤ 10 kg	1.0 ml	100 mg	500 mg	484 mg	1.0 mg
Petcuten™ Spot-on solution for dogs > 10 ≤ 25 kg	2.5 ml	250 mg	1250 mg	1210 mg	2.5 mg
Petcuten™ Spot-on solution for dogs > 25 kg ≤ 40 kg	4.0 ml	400 mg	2000 mg	1936 mg	4.0 mg
Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg	6.0 ml	600 mg	3000 mg	2904 mg	6.0 mg

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

A clear yellowish to brownish spot-on solution.

**4. INDICATIONS**

For the treatment and prevention of flea (*C. canis*, *C. felis*) infestation and for the treatment of biting lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*P. papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*A. aegypti* for two weeks and *C. pipiens* for four weeks) and against stable flies (*S. calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

Sand flies	<i>P. perniciosus</i>	3 weeks
	<i>P. papatasi</i>	2 weeks
Mosquitoes	<i>A. aegypti</i>	2 weeks
	<i>C. pipiens</i>	4 weeks
Stable flies	<i>S. calcitrans</i>	4 weeks

## 5. CONTRAINDICATIONS

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding Petcuten™ product must be used, see dosing scheme.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

## 6. ADVERSE REACTIONS

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are

generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

*Dosing Scheme*

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
4 kg and less	Petcuten™ Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
More than 4 to 10 kg	Petcuten™ Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
More than 10 to 25 kg	Petcuten™ Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
More than 25 to 40 kg	Petcuten™ Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
More than 40 to 60 kg	Petcuten™ Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

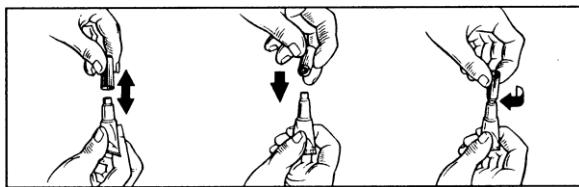
The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten™ or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

#### *Method of Administration*

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



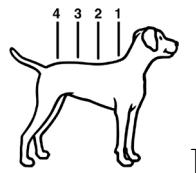
#### For dogs up to 10 kg body weight:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



#### For dogs over 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten™ pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin



## **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.

Apply only to undamaged skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

For 0.4 ml – 4.0 ml: Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.

For 6.0 ml: Use within 12 months after opening the foil pouch or before EXP, whichever is shorter.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch, or carton after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNINGS

### Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (diseases such as borreliosis, rickettsiosis, ehrlichiosis, leishmaniosis).

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

### Special precautions for use in animals

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact between the product and skin, eyes or mouth. Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician. Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

The warning below only applies to products for dogs of more than 10 kg:

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

Other precautions:

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten™ Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

The product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

Incompatibilities:

None known.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

After use, replace cap on tube. Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

#### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

#### **15. OTHER INFORMATION**

Petcuten™ Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin containing products are toxic to honey bees.

Pack sizes: 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml and 6.0 ml per pipette; packs containing 4 and 6 single-use pipette packs.

Not all pack sizes may be marketed.

## PACKAGE LEAFLET [Product in long-neck tubes]

### Petcuten™ Spot-on solution for Dogs

#### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder  
[to be completed nationally]

Distributed by:  
[to be completed nationally]

Manufacturer responsible for batch release  
KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Petcuten™ Spot-on solution for dogs up to 4 kg  
Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg  
Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg  
Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg

imidaclorpid, permethrin

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each pipette contains:

	Pipette	Imidaclorpid	Permethrin	Butylhydroxytoluene (E321)
Petcuten™ Spot-on solution for dogs ≤ 4 kg	0.4 ml	40 mg	200 mg	0.4 mg
Petcuten™ Spot-on solution for dogs > 4 ≤ 10 kg	1.0 ml	100 mg	500 mg	1.0 mg
Petcuten™ Spot-on solution for dogs > 10 ≤ 25 kg	2.5 ml	250 mg	1250 mg	2.5 mg
Petcuten™ Spot-on solution for dogs > 25 kg ≤ 40 kg	4.0 ml	400 mg	2000 mg	4.0 mg

A clear yellowish to brownish spot-on solution.

#### 4. INDICATIONS

For the treatment and prevention of flea (*C. canis*, *C. felis*) infestation and for the treatment of biting lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*P. papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*A. aegypti* for two weeks and *C. pipiens* for four weeks) and against stable flies (*S. calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

Sand flies	<i>P. perniciosus</i>	3 weeks
	<i>P. papatasi</i>	2 weeks
Mosquitoes	<i>A. aegypti</i>	2 weeks
	<i>C. pipiens</i>	4 weeks
Stable flies	<i>S. calcitrans</i>	4 weeks

## 5. CONTRAINDICATIONS

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding Petcuten™ product must be used, see dosing scheme.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

## 6. ADVERSE REACTIONS

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

### *Dosing Scheme*

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
4 kg and less	Petcuten™ Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
More than 4 to 10 kg	Petcuten™ Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
More than 10 to 25 kg	Petcuten™ Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
More than 25 to 40 kg	Petcuten™ Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
More than 40 to 60 kg	Petcuten™ Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

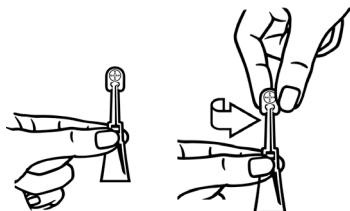
The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten™ or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

#### *Method of Administration*

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off.



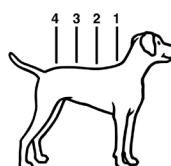
#### For dogs up to 10 kg body weight:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



#### For dogs over 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten™ pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin



## **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.

Apply only to undamaged skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not freeze.

After opening the foil pouch the product must be applied to the dog's skin.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch, or carton after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNINGS

### Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (diseases such as borrellosis, rickettsiosis, ehrlichiosis, leishmaniosis).

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

### Special precautions for use in animals:

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

#### Other precautions:

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten™ Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

#### Pregnancy and lactation:

The product can be used during pregnancy and lactation.

#### Interaction with other medicinal products and other forms of interaction:

None known.

#### Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

#### Incompatibilities:

None known.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

After use, replace cap on tube. Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

### **15. OTHER INFORMATION**

Petcuten™ Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin containing products are toxic to honey bees.

Pack sizes: 0.4 ml, 1.0 ml, 2.5 ml and 4.0 ml per pipette; packs containing 4 and 6 single-use pipette packs.

Not all pack sizes may be marketed.

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Petcuten Spot-on solution for dogs over 4 kg up to 10 kg

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 1.0 ml contains:

### Active substances:

Imidacloprid: 100.0 mg  
Permethrin (40/60): 500.0 mg

### Excipient(s):

Butylhydroxytoluene (E321): 1.0 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-on solution

Clear yellowish to brownish solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs (over 4 kg up to 10 kg)

For dogs less than or equal to 4 kg or more than 10 kg body weight, use the appropriate Petcuten Spot-on solution product (see section 4.9).

### 4.2 Indications for use, specifying the target species

For the treatment and prevention of flea (*Ctenocephalides canis*, *Ctenocephalides felis*) infestation.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

For the treatment of biting lice (*Trichodectes canis*).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks) and against stable flies (*Stomoxys calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

#### **4.3 Contraindications**

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 4 kg of weight.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats. (Refer to section 4.5 – Special precautions for use).

#### **4.4 Special warnings for each target species**

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

#### **4.5 Special precautions for use**

##### **i) Special precautions for use in animals**

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under section 4.9. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

**ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

**iii) Other precautions**

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

**4.6 Adverse reactions (frequency and seriousness)**

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy

were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

#### 4.8 Interaction with other medicinal products and other forms of interaction

None known.

#### 4.9 Amounts to be administered and administration route

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

*Dosing Scheme for Petcuten Spot-on:*

Dogs (kg body weight)	Trade name	Volume (ml)	Imidacloprid (mg/kg body weight)	Permethrin (mg/kg body weight)
≤ 4 kg	Petcuten Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
>4 kg ≤ 10 kg	Petcuten Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
>10 kg ≤ 25 kg	Petcuten Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
>25 kg ≤ 40 kg	Petcuten Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
>40 kg ≤ 60 kg	Petcuten Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten or at least 2 weeks after application, to optimise efficacy of the product.

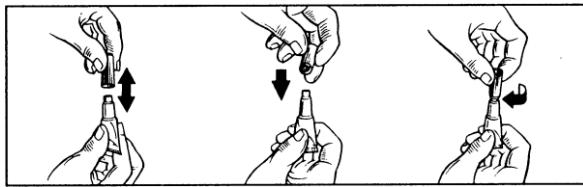
In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

For dermal use only. Apply only to undamaged skin.

#### **Method for administration for short-neck tubes**

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



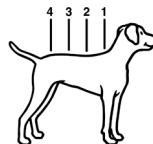
For dogs 10 kg body weight or less:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



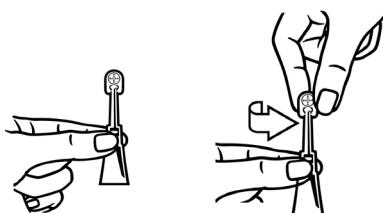
For dogs of more than 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.



#### **Method for administration for long-neck tubes**

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off.



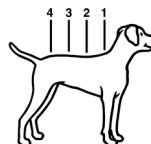
For dogs 10 kg body weight or less:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



For dogs of more than 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.



#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

#### 4.11 Withdrawal period(s)

Not applicable.

### 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic agent,  
ATC vet code: QP53AC54

Petcuten Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

#### 5.1 Pharmacodynamic properties

**Imidacloprid** is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it can be classified as a chloronicotinyl nitroguanidine. Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal. It has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) in insects. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death of the parasite.

**Permethrin** belongs to the type I class of pyrethroid acaricides and insecticides and also acts as repellent. Pyrethroids affect the voltage-gated sodium channels in vertebrates and non-vertebrates. Pyrethroids are so called "open channel blockers" affecting the sodium channel by slowing both the activation and the inactivation properties thus leading to hyperexcitability and death of the parasite.

In the combination of both substances, it has been shown Imidacloprid functions as the activator of arthropod ganglion and therefore increases the efficacy of permethrin.

The product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (e.g. borreliosis, rickettsiosis, ehrlichiosis, leishmaniosis). However, there may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. The product provides repellent (anti-feeding) activity against stable flies thereby assisting in the prevention of fly-bite dermatitis.

The product provides repellent activity (anti-feeding activity) against *Phlebotomus perniciosus* (> 80% for 3 weeks), mosquitoes and ticks. Field data from an endemic area showed that the product indirectly reduces the risk of transmission of *Leishmania infantum* from infected sandflies (*Phlebotomus perniciosus*) for up to 3 weeks, thereby reducing the risk of canine leishmaniosis in treated dogs.

## 5.2 Pharmacokinetic particulars

The product is indicated for dermal administration. Following topical application in dogs, the solution rapidly distributes over the body surface of the animal. Both active substances remain detectable on the skin and hair of the treated animal for 4 weeks.

Acute dermal studies in the rat and target animal, overdose and serum kinetic studies have established that systemic absorption of both active substances after application on intact skin is low, transient and not relevant for the clinical efficacy.

## 5.3 Environmental properties

The product should not be allowed to enter water courses as this may be dangerous for fish and aquatic organisms. For treated dogs, please see section 4.5.

Permethrin containing products are toxic to honey bees.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Butylhydroxytoluene (E321)

N-Methylpyrrolidone

Miglyol 812

Citric acid (E330)

## 6.2 Major incompatibilities

None known.

## 6.3 Shelf life

### Short-neck tube (blistered tubes in pouch):

Shelf-life of product in foil pouch: 5 years.

Shelf life of product after opening foil pouch: 2 years  
(all pipettes should be used within 2 years after opening the foil pouch or before expiry date on the pipette whichever is shorter).

Shelf-life of the broached pipette: Not applicable, once opened, the entire content of the pipette has to be applied to the animal's skin.

### Long-neck tube (individually pouched):

Shelf-life of product in foil pouch: 3 years.

Shelf-life of the broached pipette: Not applicable, once opened, the entire content of the pipette has to be applied to the dog's skin.

#### **6.4. Special precautions for storage**

Do not freeze.

Short-neck tube: After opening the foil pouch store in a dry place at a temperature not above 30°C.

Long-neck tube: After opening the foil pouch the product must be applied to the dog's skin.

#### **6.5 Nature and composition of immediate packaging**

Fill volume: 1.0 ml clear yellowish to brownish, non-aqueous solution per 1 ml pipette (100 mg imidacloprid, 500 mg permethrin).

Type of the container: White polypropylene pipette.  
Short-neck tube: White polypropylene cap.  
Long-neck tube: Transparent cap.

Material of the secondary packaging: Short-neck tube:  
Polychlorotrifluoroethylene PCTFE/PVC heat sealed blister packs in one or more aluminium pouch(es) and a cardboard box.

Long-neck tube:  
Single aluminium pouch(es) in a cardboard box.

Package sizes: Packs containing 4 and 6 unit dose pipettes. Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

After use, replace cap on tube. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

### **7. MARKETING AUTHORISATION HOLDER**

*[to be completed nationally]*

### **8. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

### **10. DATE OF REVISION OF THE TEXT**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

### **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Outer carton, pack size of 4 and 6 pipettes – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 1.0 ml pipette contains:

Active substances: 100 mg imidacloprid, 500 mg permethrin

**3. PHARMACEUTICAL FORM**

Spot-on solution

**4. PACKAGE SIZE**

4 pipettes (4x 1.0 ml)

6 pipettes (6x 1.0 ml)

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

[For cartons: this text for front (only) of carton.]

- Eliminates ticks, fleas and biting lice
- Repels ticks, mosquitos, sand flies, and stable flies
- Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

[For cartons: this text for back (only) of carton]

- Eliminates fleas (treatment and prevention); can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and eliminates ticks; reducing the risk of transmission of CVBD (diseases such as borreliosis, rickettsiosis, and ehrlichiosis).
- Repels mosquitoes and sand flies; reducing the risk of transmission of leishmaniosis.
- Repels stable flies; contributing to the prevention of fly-bite dermatitis.

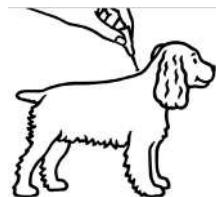
**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

**Read the package leaflet before use.**

Keep the foil pouch with the blisters in the outer carton.

[Dog Application –Pictogram (size specific corresponding to the product size)]



#### **8. WITHDRAWAL PERIOD(S)**

#### **9. SPECIAL WARNING(S), IF NECESSARY**

**Read the package leaflet before use.**

Do not use on puppies of less than 7 weeks of age or 4 kg of weight.

**Do not use on cats.**

[Do Not Use on Cats -Pictogram]



#### **10. EXPIRY DATE**

Expiry/EXP {month/year}

Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.

#### **11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

#### **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

#### **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only

*[Prescription status to be completed nationally]*

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:  
*[to be completed nationally]*

Distributed by:  
*[to be completed nationally]*

**16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**17. MANUFACTURER'S BATCH NUMBER**

Batch No./Lot {number}



[Note: Depending on prevalent pests in CMSs, not all target pest pictograms may be used in every country]

[Figure of pipette, photo of dog]

Other Information:

- Remains effective if the dog becomes wet.
- Provides a larvicidal effect against fleas in the immediate surroundings of the treated dogs
- Can be used on both pregnant and lactating bitches.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****Outer carton, pack size of 4 and 6 pipettes – Product in long-neck tubes****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 1.0 ml pipette contains:

Active substances: 100 mg imidacloprid, 500 mg permethrin

**3. PHARMACEUTICAL FORM**

Spot-on solution

**4. PACKAGE SIZE**

4 pipettes (4x 1.0 ml)  
6 pipettes (6x 1.0 ml)

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

[For cartons: this text for front (only) of carton.]

- Eliminates ticks, fleas and biting lice
- Repels ticks, mosquitos, sand flies, and stable flies
- Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

[For cartons: this text for back (only) of carton]

- Eliminates fleas (treatment and prevention); can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and eliminates ticks; reducing the risk of transmission of CVBD (diseases such as borreliosis, rickettsiosis, and ehrlichiosis).
- Repels mosquitoes and sand flies; reducing the risk of transmission of leishmaniosis.
- Repels stable flies; contributing to the prevention of fly-bite dermatitis.

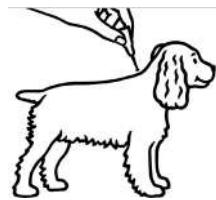
**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

**Read the package leaflet before use.**

Keep the foil pouch(es) in the outer carton.

[Dog Application –Pictogram (size specific corresponding to the product size)]



#### **8. WITHDRAWAL PERIOD(S)**

#### **9. SPECIAL WARNING(S), IF NECESSARY**

**Read the package leaflet before use.**

Do not use on puppies of less than 7 weeks of age or 4 kg of weight.

**Do not use on cats.**

[Do Not Use on Cats -Pictogram]



#### **10. EXPIRY DATE**

Expiry/EXP {month/year}

#### **11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

After opening the foil pouch the product must be applied to the dog's skin.

#### **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

#### **13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only

*[Prescription status to be completed nationally]*

#### **14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"**

Keep out of the sight and reach of children.

#### **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:  
*[to be completed nationally]*

Distributed by:  
*[to be completed nationally]*

#### **16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

#### **17. MANUFACTURER'S BATCH NUMBER**

Batch No./Lot {number}



[Note: Depending on prevalent pests in CMSs, not all target pest pictograms may be used in every country]

[Figure of pipette, photo of dog]

Other Information:

- Remains effective if the dog becomes wet.
- Provides a larvicultural effect against fleas in the immediate surroundings of the treated dogs
- Can be used on both pregnant and lactating bitches.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Pipette label – international version (no translation required) – Product in short-neck tubes and long-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

100 mg/ml imidacloprid(e)

500 mg/ml permethrin(e)

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

1.0 ml

**4. ROUTE(S) OF ADMINISTRATION****5. WITHDRAWAL PERIOD(S)****6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size]



[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister – international version (no translation required) – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

**4. BATCH NUMBER**

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]



> 4 kg ≤ 10 kg  
1.0 ml

[Tube-picto]



[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Foil pouch – international version (no further translation required) – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

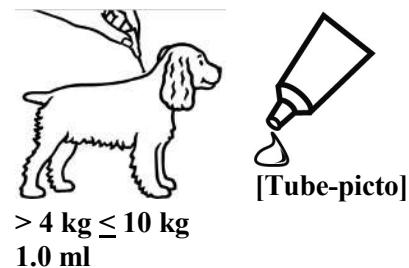
EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]

**FURTHER INFORMATION**

[Do Not Use on Cats -Pictogram]



Country code	
----	Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.
IT	Utilizzare entro 24 mesi dopo l'apertura della busta di alluminio o

	prima della data di scadenza (EXP) qualora sia più breve.
NL	Gebruiken binnen 24 maanden na opening van het zakje of vóór EXP, het kortste van de twee.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS****Foil pouch – international version (no further translation required) – Product in long-neck tubes****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]



> 4 kg  $\leq$  10 kg  
1.0 ml



[Tube-picto]

**FURTHER INFORMATION**

[Do Not Use on Cats -Pictogram]



After opening the foil pouch the product must be applied to the dog's skin.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET [Product in short-neck tubes]**

**Petcuten™ Spot-on solution for Dogs**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder  
*[to be completed nationally]*

Distributed by:  
*[to be completed nationally]*

Manufacturer responsible for batch release  
KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs up to 4 kg  
Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg  
Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg  
Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg  
Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg

imidacloprid, permethrin

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each pipette contains:

	<b>Pipette</b>	<b>Imidacloprid</b>	<b>Permethrin</b>	<b>N-Methylpyrrolidone</b>	<b>Butylhydroxytoluene (E321)</b>
Petcuten™ Spot-on solution for dogs≤ 4 kg	0.4 ml	40 mg	200 mg	194 mg	0.4 mg
Petcuten™ Spot-on solution for dogs > 4 ≤ 10 kg	1.0 ml	100 mg	500 mg	484 mg	1.0 mg
Petcuten™ Spot-on solution for dogs > 10 ≤ 25 kg	2.5 ml	250 mg	1250 mg	1210 mg	2.5 mg
Petcuten™ Spot-on solution for dogs > 25 kg ≤ 40 kg	4.0 ml	400 mg	2000 mg	1936 mg	4.0 mg
Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg	6.0 ml	600 mg	3000 mg	2904 mg	6.0 mg

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

A clear yellowish to brownish spot-on solution.

## 4. INDICATIONS

For the treatment and prevention of flea (*C. canis*, *C. felis*) infestation and for the treatment of biting lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*P. papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*A. aegypti* for two weeks and *C. pipiens* for four weeks) and against stable flies (*S. calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

Sand flies	<i>P. perniciosus</i>	3 weeks
	<i>P. papatasi</i>	2 weeks
Mosquitoes	<i>A. aegypti</i>	2 weeks
	<i>C. pipiens</i>	4 weeks
Stable flies	<i>S. calcitrans</i>	4 weeks

## 5. CONTRAINDICATIONS

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding Petcuten™ product must be used, see dosing scheme.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

## 6. ADVERSE REACTIONS

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as

unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

*Dosing Scheme*

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
4 kg and less	Petcuten™ Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
More than 4 to 10 kg	Petcuten™ Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
More than 10 to 25 kg	Petcuten™ Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
More than 25 to 40 kg	Petcuten™ Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
More than 40 to 60 kg	Petcuten™ Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

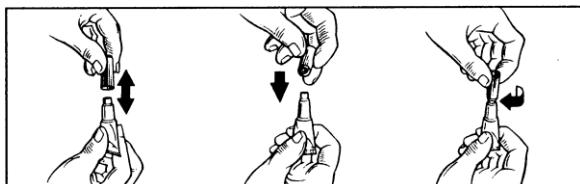
The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten™ or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

#### *Method of Administration*

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



#### For dogs up to 10 kg body weight:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



#### For dogs over 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten™ pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin



### **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.

Apply only to undamaged skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

### **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

For 0.4 ml – 4.0 ml: Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch, or carton after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNINGS

### Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (diseases such as borreliosis, rickettsiosis, ehrlichiosis, leishmaniosis).

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

### Special precautions for use in animals

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

The warning below only applies to products for dogs of more than 10 kg:

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

Other precautions:

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten™ Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

The product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

Incompatibilities:

None known.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

After use, replace cap on tube.

Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

#### **14. OTHER INFORMATION**

Petcuten™ Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin containing products are toxic to honey bees.

Pack sizes: 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml and 6.0 ml per pipette; packs containing 4 and 6 single-use pipette packs.

Not all pack sizes may be marketed.

## PACKAGE LEAFLET [Product in long-neck tubes]

### Petcuten™ Spot-on solution for Dogs

#### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder  
[to be completed nationally]

Distributed by:  
[to be completed nationally]

Manufacturer responsible for batch release  
KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Petcuten™ Spot-on solution for dogs up to 4 kg  
Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg  
Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg  
Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg

imidaclorpid, permethrin

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each pipette contains:

	Pipette	Imidaclorpid	Permethrin	N-Methylpyrrolidone	Butylhydroxytoluene (E321)
Petcuten™ Spot-on solution for dogs $\leq$ 4 kg	0.4 ml	40 mg	200 mg	194 mg	0.4 mg
Petcuten™ Spot-on solution for dogs $4 \leq$ 10 kg	1.0 ml	100 mg	500 mg	484 mg	1.0 mg
Petcuten™ Spot-on solution for dogs $10 \leq$ 25 kg	2.5 ml	250 mg	1250 mg	1210 mg	2.5 mg
Petcuten™ Spot-on solution for dogs $25 \leq$ 40 kg	4.0 ml	400 mg	2000 mg	1936 mg	4.0 mg

A clear yellowish to brownish spot-on solution.

#### 4. INDICATIONS

For the treatment and prevention of flea (*C. canis*, *C. felis*) infestation and for the treatment of biting lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*P. papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*A. aegypti* for two weeks and *C. pipiens* for four weeks) and against stable flies (*S. calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

Sand flies	<i>P. perniciosus</i>	3 weeks
	<i>P. papatasi</i>	2 weeks
Mosquitoes	<i>A. aegypti</i>	2 weeks
	<i>C. pipiens</i>	4 weeks
Stable flies	<i>S. calcitrans</i>	4 weeks

## 5. CONTRAINDICATIONS

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding Petcuten™ product must be used, see dosing scheme.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

## 6. ADVERSE REACTIONS

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

### *Dosing Scheme*

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
4 kg and less	Petcuten™ Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
More than 4 to 10 kg	Petcuten™ Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
More than 10 to 25 kg	Petcuten™ Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
More than 25 to 40 kg	Petcuten™ Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
More than 40 to 60 kg	Petcuten™ Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

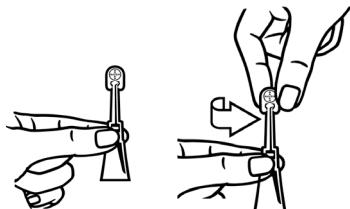
The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten™ or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

#### *Method of Administration*

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off.



#### For dogs up to 10 kg body weight:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



#### For dogs over 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten™ pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin



### **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.

Apply only to undamaged skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

### **10. WITHDRAWAL PERIOD(S)**

Not applicable.

### **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not freeze.

After opening the foil pouch the product must be applied to the dog's skin.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch, or carton after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNINGS

### Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (diseases such as borrellosis, rickettsiosis, ehrlichiosis, leishmaniosis).

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

### Special precautions for use in animals:

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

The warning below only applies to products for dogs of more than 10 kg:

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

#### Other precautions:

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten™ Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

#### Pregnancy and lactation:

The product can be used during pregnancy and lactation.

#### Interaction with other medicinal products and other forms of interaction:

None known.

#### Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

#### Incompatibilities:

None known.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

After use, replace cap on tube. Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

## **15. OTHER INFORMATION**

Petcuten™ Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin containing products are toxic to honey bees.

Pack sizes: 0.4 ml, 1.0 ml, 2.5 ml and 4.0 ml per pipette; packs containing 4 and 6 single-use pipette packs.

Not all pack sizes may be marketed.

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Petcuten Spot-on solution for dogs over 10 kg up to 25 kg

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 2.5 ml contains:

### Active substances:

Imidacloprid:	250.0 mg
Permethrin (40/60):	1250.0 mg

### Excipient(s):

N-Methylpyrrolidone:	1210 mg
Butylhydroxytoluene (E321):	2.5 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-on solution

Clear yellowish to brownish solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs (over 10 kg up to 25 kg)

For dogs less than or equal to 10 kg or more than 25 kg body weight, use the appropriate Petcuten Spot-on solution product (see section 4.9).

### 4.2 Indications for use, specifying the target species

For the treatment and prevention of flea (*Ctenocephalides canis*, *Ctenocephalides felis*) infestation.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

For the treatment of biting lice (*Trichodectes canis*).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks) and against stable flies (*Stomoxys calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

#### **4.3 Contraindications**

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 10 kg of weight.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats. (Refer to section 4.5 – Special precautions for use).

#### **4.4 Special warnings for each target species**

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

#### **4.5 Special precautions for use**

##### **i) Special precautions for use in animals**

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under section 4.9. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

**ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

**iii) Other precautions**

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

**4.6 Adverse reactions (frequency and seriousness)**

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

#### 4.8 Interaction with other medicinal products and other forms of interaction

None known.

#### 4.9 Amounts to be administered and administration route

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

*Dosing Scheme for Petcuten Spot-on:*

Dogs (kg body weight)	Trade name	Volume (ml)	Imidacloprid (mg/kg body weight)	Permethrin (mg/kg body weight)
≤ 4 kg	Petcuten Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
>4 kg ≤ 10 kg	Petcuten Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
>10 kg ≤ 25 kg	Petcuten Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
>25 kg ≤ 40 kg	Petcuten Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
>40 kg ≤ 60 kg	Petcuten Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50- 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten or at least 2 weeks after application, to optimise efficacy of the product.

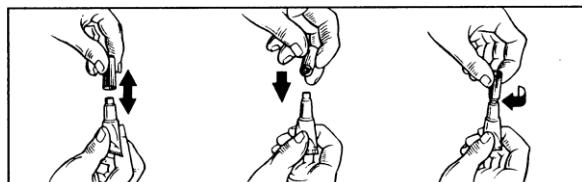
In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

For dermal use only. Apply only to undamaged skin.

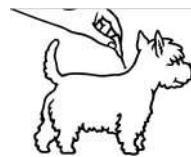
#### Method for administration for short-neck tubes

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



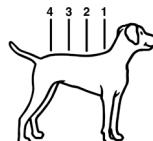
For dogs 10 kg body weight or less:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



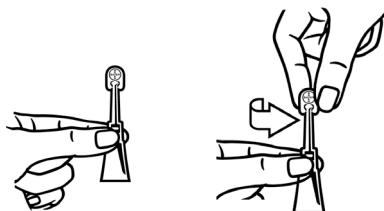
For dogs of more than 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.



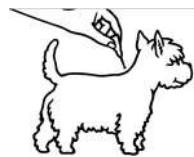
#### **Method for administration for long-neck tubes**

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off.



For dogs 10 kg body weight or less:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



For dogs of more than 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog



#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

#### 4.11 Withdrawal period(s)

Not applicable.

### 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic agent,  
ATC vet code: QP53AC54

Petcuten Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

#### 5.1 Pharmacodynamic properties

**Imidacloprid** is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it can be classified as a chloronicotinyl nitroguanidine. Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal. It has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) in insects. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death of the parasite.

**Permethrin** belongs to the type I class of pyrethroid acaricides and insecticides and also acts as repellent. Pyrethroids affect the voltage-gated sodium channels in vertebrates and non-vertebrates. Pyrethroids are so called "open channel blockers" affecting the sodium channel by slowing both the activation and the inactivation properties thus leading to hyperexcitability and death of the parasite.

In the combination of both substances, it has been shown Imidacloprid functions as the activator of arthropod ganglion and therefore increases the efficacy of permethrin.

The product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (e.g. borrellosis, rickettsiosis, ehrlichiosis, leishmaniosis). However, there may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. The product provides repellent (anti-feeding) activity against stable flies thereby assisting in the prevention of fly-bite dermatitis.

The product provides repellent activity (anti-feeding activity) against *Phlebotomus perniciosus* (> 80% for 3 weeks), mosquitoes and ticks. Field data from an endemic area showed that the product indirectly reduces the risk of transmission of *Leishmania infantum* from infected sandflies (*Phlebotomus perniciosus*) for up to 3 weeks, thereby reducing the risk of canine leishmaniosis in treated dogs.

## 5.2 Pharmacokinetic particulars

The product is indicated for dermal administration. Following topical application in dogs, the solution rapidly distributes over the body surface of the animal. Both active substances remain detectable on the skin and hair of the treated animal for 4 weeks.

Acute dermal studies in the rat and target animal, overdose and serum kinetic studies have established that systemic absorption of both active substances after application on intact skin is low, transient and not relevant for the clinical efficacy.

## 5.3 Environmental properties

The product should not be allowed to enter water courses as this may be dangerous for fish and aquatic organisms. For treated dogs, please see section 4.5.

Permethrin containing products are toxic to honey bees.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Butylhydroxytoluene (E321)  
N-Methylpyrrolidone  
Miglyol 812Citric acid (E330)

## 6.2 Major incompatibilities

None known.

## 6.3 Shelf life

### Short-neck tube (blistered tubes in pouch):

Shelf-life of product in foil pouch: 5 years.

Shelf life of product after opening foil pouch: 2 years  
(all pipettes should be used within 2 years after opening the foil pouch or before expiry date on the pipette whichever is shorter).

Shelf-life of the broached pipette: Not applicable, once opened, the entire content of the pipette has to be applied to the animal's skin.

**Long-neck tube (individually pouched):**

Shelf-life of product in foil pouch:	3 years.
Shelf-life of the broached pipette:	Not applicable, once opened, the entire content of the pipette has to be applied to the dog's skin.

**6.4. Special precautions for storage**

Do not freeze.

Short-neck tube: After opening the foil pouch store in a dry place at a temperature not above 30°C.

Long-neck tube: After opening the foil pouch the product must be applied to the dog's skin.

**6.5 Nature and composition of immediate packaging**

Fill volume:	2.5 ml clear yellowish to brownish, non-aqueous solution per 2.5 ml pipette (250 mg imidacloprid, 1250 mg permethrin).
Type of the container:	White polypropylene pipette. Short-neck tube: White polypropylene cap. Long-neck tube: Transparent cap.
Material of the secondary packaging:	Short-neck tube: Polychlorotrifluoroethylene PCTFE/PVC heat sealed blister packs in one or more aluminium pouch(es) and a cardboard box.
	Long-neck tube: Single aluminium pouch(es) in a cardboard box.
Package sizes:	Packs containing 4 and 6 unit dose pipettes. Not all pack sizes may be marketed.

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

After use, replace cap on tube. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

*[to be completed nationally]*

**8. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

## **10. DATE OF REVISION OF THE TEXT**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

## **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****Outer carton, pack size of 4 and 6 pipettes – Product in short-neck tubes****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 2.5 ml pipette contains:

Active substances: 250 mg imidacloprid, 1250 mg permethrin

**3. PHARMACEUTICAL FORM**

Spot-on solution

**4. PACKAGE SIZE**4 pipettes (4x 2.5 ml)  
6 pipettes (6x 2.5 ml)**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

[For cartons: this text for front (only) of carton.]

- Eliminates ticks, fleas and biting lice
- Repels ticks, mosquitos, sand flies, and stable flies
- Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

[For cartons: this text for back (only) of carton]

- Eliminates fleas (treatment and prevention); can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and eliminates ticks; reducing the risk of transmission of CVBD (diseases such as borreliosis, rickettsiosis, and ehrlichiosis).
- Repels mosquitoes and sand flies; reducing the risk of transmission of leishmaniosis.
- Repels stable flies; contributing to the prevention of fly-bite dermatitis.

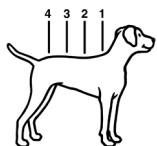
**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

**Read the package leaflet before use.**

Keep the foil pouch with the blisters in the outer carton.

[Dog Application –Pictogram (size specific corresponding to the product size)]



## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

**Read the package leaflet before use.**

Do not use on puppies of less than 7 weeks of age or 10 kg of weight.

**Do not use on cats.**

[Do Not Use on Cats -Pictogram]



## 10. EXPIRY DATE

Expiry/EXP {month/year}

Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.

## 11. SPECIAL STORAGE CONDITIONS

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

*[Prescription status to be completed nationally]*

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:

*[to be completed nationally]*

Distributed by:

*[to be completed nationally]*

**16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**17. MANUFACTURER'S BATCH NUMBER**

Batch No./Lot {number}



[Note: Depending on prevalent pests in CMSs, not all target pest pictograms may be used in every country]

[Figure of pipette, photo of dog]

Other Information:

- Remains effective if the dog becomes wet.
- Provides a larvicidal effect against fleas in the immediate surroundings of the treated dogs
- Can be used on both pregnant and lactating bitches.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****Outer carton, pack size of 4 and 6 pipettes – Product in long-neck tubes****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 2.5 ml pipette contains:

Active substances: 250 mg imidacloprid, 1250 mg permethrin

**3. PHARMACEUTICAL FORM**

Spot-on solution

**4. PACKAGE SIZE**

4 pipettes (4x 2.5 ml)  
6 pipettes (6x 2.5 ml)

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

[For cartons: this text for front (only) of carton.]

- Eliminates ticks, fleas and biting lice
- Repels ticks, mosquitos, sand flies, and stable flies
- Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

[For cartons: this text for back (only) of carton]

- Eliminates fleas (treatment and prevention); can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and eliminates ticks; reducing the risk of transmission of CVBD (diseases such as borreliosis, rickettsiosis, and ehrlichiosis).
- Repels mosquitoes and sand flies; reducing the risk of transmission of leishmaniosis.
- Repels stable flies; contributing to the prevention of fly-bite dermatitis.

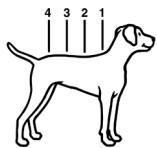
**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

**Read the package leaflet before use.**

Keep the foil pouch(es) in the outer carton.

[Dog Application –Pictogram (size specific corresponding to the product size)]



#### **8. WITHDRAWAL PERIOD(S)**

#### **9. SPECIAL WARNING(S), IF NECESSARY**

**Read the package leaflet before use.**

Do not use on puppies of less than 7 weeks of age or 10 kg of weight.

**Do not use on cats.**

[Do Not Use on Cats -Pictogram]



#### **10. EXPIRY DATE**

Expiry/EXP {month/year}

#### **11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

After opening the foil pouch the product must be applied to the dog's skin.

#### **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

#### **13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only

*[Prescription status to be completed nationally]*

#### **14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:  
*[to be completed nationally]*

Distributed by:  
*[to be completed nationally]*

**16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**17. MANUFACTURER'S BATCH NUMBER**

Batch No./Lot {number}



[Note: Depending on prevalent pests in CMSs, not all target pest pictograms may be used in every country]

[Figure of pipette, photo of dog]

Other Information:

- Remains effective if the dog becomes wet.
- Provides a larvicidal effect against fleas in the immediate surroundings of the treated dogs
- Can be used on both pregnant and lactating bitches.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Pipette label – international version (no translation required) – Product in short-neck tubes and long-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

100 mg/ml imidacloprid(e)

500 mg/ml permethrin(e)

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

2.5 ml

**4. ROUTE(S) OF ADMINISTRATION****5. WITHDRAWAL PERIOD(S)****6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size]



> 10 kg ≤ 25 kg

[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister – international version (no translation required) – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

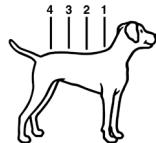
Distributed by [to be completed]

**3. EXPIRY DATE**

**4. BATCH NUMBER**

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]



> 10 kg ≤ 25 kg

2.5 ml

[Tube-picto]



[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Foil pouch – international version (no further translation required) – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

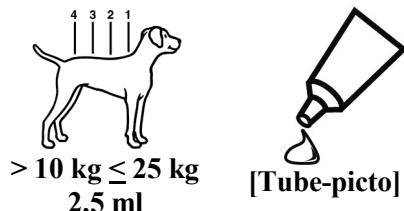
EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]

**FURTHER INFORMATION**

[Do Not Use on Cats -Pictogram]



Country code	
---	Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.
IT	Utilizzare entro 24 mesi dopo l'apertura della busta di alluminio o prima della data di scadenza (EXP) qualora sia più breve.
NL	Gebruiken binnen 24 maanden na opening van het zakje of vóór EXP, het kortste van de twee.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS****Foil pouch – international version (no further translation required) – Product in long-neck tubes****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

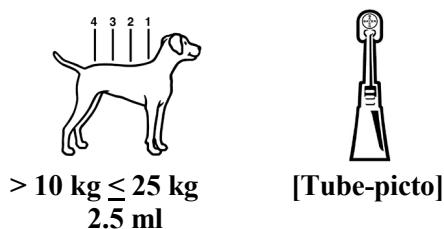
EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]

**FURTHER INFORMATION**

[Do Not Use on Cats -Pictogram]



After opening the foil pouch the product must be applied to the dog's skin.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET [Product in short-neck tubes]**

**Petcuten™ Spot-on solution for Dogs**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder  
[to be completed nationally]

Distributed by:  
[to be completed nationally]

Manufacturer responsible for batch release  
KVP Pharma + Veterinär Produkte GmbH

Projensdorfer Str. 324, 24106 Kiel  
Germany

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs up to 4 kg

Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg

Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg

Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg

Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg

imidacloprid, permethrin

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each pipette contains:

	<b>Pipette</b>	<b>Imidacloprid</b>	<b>Permethrin</b>	<b>N-Methylpyrrolidone</b>	<b>Butylhydroxytoluene (E321)</b>
Petcuten™ Spot-on solution for dogs ≤ 4 kg	0.4 ml	40 mg	200 mg	194 mg	0.4 mg
Petcuten™ Spot-on solution for dogs > 4 ≤ 10 kg	1.0 ml	100 mg	500 mg	484 mg	1.0 mg
Petcuten™ Spot-on solution for dogs > 10 ≤ 25 kg	2.5 ml	250 mg	1250 mg	1210 mg	2.5 mg
Petcuten™ Spot-on solution for dogs > 25 kg ≤ 40 kg	4.0 ml	400 mg	2000 mg	1936 mg	4.0 mg
Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg	6.0 ml	600 mg	3000 mg	2904 mg	6.0 mg

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

A clear yellowish to brownish spot-on solution.

#### 4. INDICATIONS

For the treatment and prevention of flea (*C. canis*, *C. felis*) infestation and for the treatment of biting lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*P. papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*A. aegypti* for two weeks and *C. pipiens* for four weeks) and against stable flies (*S. calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

Sand flies	<i>P. perniciosus</i>	3 weeks
	<i>P. papatasi</i>	2 weeks
Mosquitoes	<i>A. aegypti</i>	2 weeks
	<i>C. pipiens</i>	4 weeks
Stable flies	<i>S. calcitrans</i>	4 weeks

#### 5. CONTRAINDICATIONS

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding Petcuten™ product must be used, see dosing scheme.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

#### 6. ADVERSE REACTIONS

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as

unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

### *Dosing Scheme*

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
4 kg and less	Petcuten™ Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
More than 4 to 10 kg	Petcuten™ Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
More than 10 to 25 kg	Petcuten™ Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
More than 25 to 40 kg	Petcuten™ Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
More than 40 to 60 kg	Petcuten™ Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

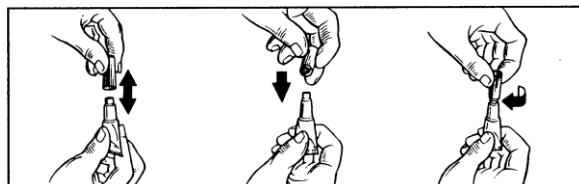
The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten™ or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

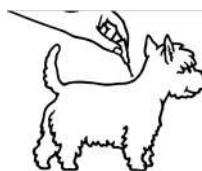
#### *Method of Administration*

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



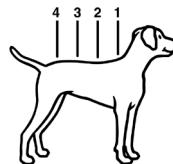
#### For dogs up to 10 kg body weight:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



#### For dogs over 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten™ pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin



## **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.

Apply only to undamaged skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

For 0.4 ml – 4.0 ml: Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.

For 6.0 ml: Use within 12 months after opening the foil pouch or before EXP, whichever is shorter.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch, or carton after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNINGS

### Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (diseases such as borrellosis, rickettsiosis, ehrlichiosis, leishmaniosis).

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

### Special precautions for use in animals:

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

The warning below only applies to products for dogs of more than 10 kg:

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

Other precautions:

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten™ Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

The product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

Incompatibilities:

None known.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

After use, replace cap on tube. Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

### **15. OTHER INFORMATION**

Petcuten™ Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin containing products are toxic to honey bees.

Pack sizes: 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml and 6.0 ml per pipette; packs containing 4 and 6 single-use pipette packs.

Not all pack sizes may be marketed.

## PACKAGE LEAFLET [Product in long-neck tubes]

### Petcuten™ Spot-on solution for Dogs

#### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder  
[to be completed nationally]

Distributed by:  
[to be completed nationally]

Manufacturer responsible for batch release  
KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Petcuten™ Spot-on solution for dogs up to 4 kg  
Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg  
Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg  
Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg

imidacloprid, permethrin

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each pipette contains:

	Pipette	Imidaclo prid	Permethrin	N- Methyldi pyrrolidone	Butylhydrox yt oluene (E321)
Petcuten™ Spot-on solution for dogs ≤ 4 kg	0.4 ml	40 mg	200 mg	194 mg	0.4 mg
Petcuten™ Spot-on solution for dogs > 4 ≤ 10 kg	1.0 ml	100 mg	500 mg	484 mg	1.0 mg
Petcuten™ Spot-on solution for dogs > 10 ≤ 25 kg	2.5 ml	250 mg	1250 mg	1210 mg	2.5 mg
Petcuten™ Spot-on solution for dogs > 25 kg ≤ 40 kg	4.0 ml	400 mg	2000 mg	1936 mg	4.0 mg

A clear yellowish to brownish spot-on solution.

#### 4. INDICATIONS

For the treatment and prevention of flea (*C. canis*, *C. felis*) infestation and for the treatment of biting lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*P. papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*A. aegypti* for two weeks and *C. pipiens* for four weeks) and against stable flies (*S. calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

Sand flies	<i>P. perniciosus</i>	3 weeks
	<i>P. papatasi</i>	2 weeks
Mosquitoes	<i>A. aegypti</i>	2 weeks
	<i>C. pipiens</i>	4 weeks
Stable flies	<i>S. calcitrans</i>	4 weeks

## 5. CONTRAINDICATIONS

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding Petcuten™ product must be used, see dosing scheme.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

## 6. ADVERSE REACTIONS

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

### *Dosing Scheme*

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
4 kg and less	Petcuten™ Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
More than 4 to 10 kg	Petcuten™ Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
More than 10 to 25 kg	Petcuten™ Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
More than 25 to 40 kg	Petcuten™ Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
More than 40 to 60 kg	Petcuten™ Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

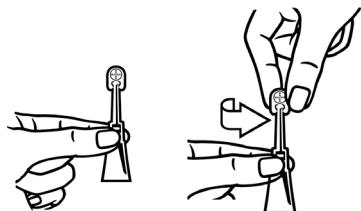
The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten™ or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

#### *Method of Administration*

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off.



#### For dogs up to 10 kg body weight:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



#### For dogs over 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten™ pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin



### **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.

Apply only to undamaged skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

### **10. WITHDRAWAL PERIOD(S)**

Not applicable.

### **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not freeze.

After opening the foil pouch the product must be applied to the dog's skin.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch, or carton after EXP. The expiry date refers to the last day of that month.

## **12. SPECIAL WARNINGS**

### Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (diseases such as borreliosis, rickettsiosis, ehrlichiosis, leishmaniosis).

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

### Special precautions for use in animals

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

The warning below only applies to products for dogs of more than 10 kg:

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

#### Other precautions:

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten™ Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

#### Pregnancy and lactation:

The product can be used during pregnancy and lactation.

#### Interaction with other medicinal products and other forms of interaction:

None known.

#### Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

#### Incompatibilities:

None known.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

After use, replace cap on tube. Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

## **15. OTHER INFORMATION**

Petcuten™ Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin containing products are toxic to honey bees.

Pack sizes: 0.4 ml, 1.0 ml, 2.5 ml and 4.0 ml per pipette; packs containing 4 and 6 single-use pipette packs.

Not all pack sizes may be marketed.

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Petcuten Spot-on solution for dogs over 25 kg up to 40 kg

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 4.0 ml contains:

### Active substances:

Imidacloprid:	400.0 mg
Permethrin (40/60):	2000.0 mg

### Excipient(s):

N-Methylpyrrolidone:	1936 mg
Butylhydroxytoluene (E321):	4.0 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-on solution

Clear yellowish to brownish solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs (over 25 kg up to 40 kg)

For dogs less than or equal to 25 kg or more than 40 kg body weight, use the appropriate Petcuten Spot-on solution product (see section 4.9).

### 4.2 Indications for use, specifying the target species

For the treatment and prevention of flea (*Ctenocephalides canis*, *Ctenocephalides felis*) infestation.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

For the treatment of biting lice (*Trichodectes canis*).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks) and against stable flies (*Stomoxys calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

#### **4.3 Contraindications**

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 25 kg of weight.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats. (Refer to section 4.5 – Special precautions for use).

#### **4.4 Special warnings for each target species**

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

#### **4.5 Special precautions for use**

##### **i) Special precautions for use in animals**

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under section 4.9. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

**ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

**iii) Other precautions**

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

**4.6 Adverse reactions (frequency and seriousness)**

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

#### 4.8 Interaction with other medicinal products and other forms of interaction

None known.

#### 4.9 Amounts to be administered and administration route

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

*Dosing Scheme for Petcuten Spot-on:*

Dogs (kg body weight)	Trade name	Volume (ml)	Imidacloprid (mg/kg body weight)	Permethrin (mg/kg body weight)
≤ 4 kg	Petcuten Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
>4 kg ≤ 10 kg	Petcuten Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
>10 kg ≤ 25 kg	Petcuten Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
>25 kg ≤ 40 kg	Petcuten Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
>40 kg ≤ 60 kg	Petcuten Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50- 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

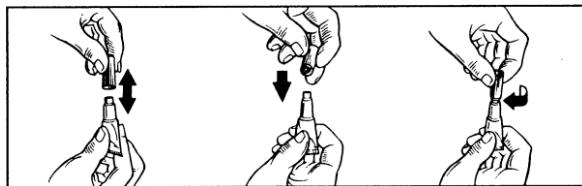
To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

For dermal use only. Apply only to undamaged skin.

#### Method for administration for short-neck tubes

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull

cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



For dogs 10 kg body weight or less:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



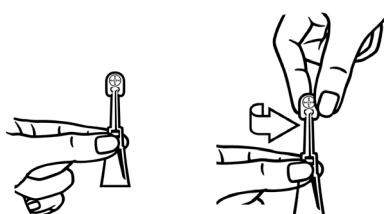
For dogs of more than 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.



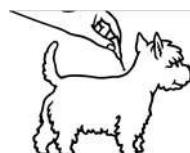
#### **Method for administration for long-neck tubes**

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off.



For dogs 10 kg body weight or less:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



For dogs of more than 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.



#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

#### 4.11 Withdrawal period(s)

Not applicable.

### 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic agent,  
ATC vet code: QP53AC54

Petcuten Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

#### 5.1 Pharmacodynamic properties

**Imidacloprid** is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it can be classified as a chloronicotinyl nitroguanidine. Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal. It has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) in insects. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death of the parasite.

**Permethrin** belongs to the type I class of pyrethroid acaricides and insecticides and also acts as repellent. Pyrethroids affect the voltage-gated sodium channels in vertebrates and non-vertebrates. Pyrethroids are so called "open channel blockers" affecting the sodium channel by slowing both the activation and the inactivation properties thus leading to hyperexcitability and death of the parasite.

In the combination of both substances, it has been shown Imidacloprid functions as the activator of arthropod ganglion and therefore increases the efficacy of permethrin.

The product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (e.g. borreliosis, rickettsiosis, ehrlichiosis, leishmaniosis). However, there may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. The product provides repellent (anti-feeding) activity against stable flies thereby assisting in the prevention of fly-bite dermatitis.

The product provides repellent activity (anti-feeding activity) against *Phlebotomus perniciosus* (> 80% for 3 weeks), mosquitoes and ticks. Field data from an endemic area showed that the product indirectly reduces the risk of transmission of *Leishmania infantum* from infected sandflies (*Phlebotomus perniciosus*) for up to 3 weeks, thereby reducing the risk of canine leishmaniosis in treated dogs.

## 5.2 Pharmacokinetic particulars

The product is indicated for dermal administration. Following topical application in dogs, the solution rapidly distributes over the body surface of the animal. Both active substances remain detectable on the skin and hair of the treated animal for 4 weeks.

Acute dermal studies in the rat and target animal, overdose and serum kinetic studies have established that systemic absorption of both active substances after application on intact skin is low, transient and not relevant for the clinical efficacy.

## 5.3 Environmental properties

The product should not be allowed to enter water courses as this may be dangerous for fish and aquatic organisms. For treated dogs, please see section 4.5.

Permethrin containing products are toxic to honey bees.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Butylhydroxytoluene (E321)

N-Methylpyrrolidone

Miglyol 812

Citric acid (E330)

## 6.2 Major incompatibilities

None known.

## 6.3 Shelf life

### Short-neck tube (blistered tubes in pouch):

Shelf-life of product in foil pouch: 5 years.

Shelf life of product after opening foil pouch: 2 years  
(all pipettes should be used within 2 years after opening the foil pouch or before expiry date on the pipette whichever is shorter).

Shelf-life of the broached pipette: Not applicable, once opened, the entire content of the pipette has to be applied to the animal's skin.

### Long-neck tube (individually pouched):

Shelf-life of product in foil pouch: 3 years.

Shelf-life of the broached pipette: Not applicable, once opened, the entire content of the pipette has to be applied to the dog's skin.

#### **6.4. Special precautions for storage**

Do not freeze.

Short-neck tube: After opening the foil pouch store in a dry place at a temperature not above 30°C.

Long-neck tube: After opening the foil pouch the product must be applied to the dog's skin.

#### **6.5 Nature and composition of immediate packaging**

Fill volume:	4.0 ml clear yellowish to brownish, non-aqueous solution per 4 ml pipette (400 mg imidacloprid, 2000 mg permethrin).
Type of the container:	White polypropylene pipette. Short-neck tube: White polypropylene cap. Long-neck tube: Transparent cap.
Material of the secondary packaging:	Short-neck tube: Polychlorotrifluoroethylene PCTFE/PVC heat sealed blister packs in one or more aluminium pouch(es) and a cardboard box.
	Long-neck tube: Single aluminium pouch(es) in a cardboard box.
Package sizes:	Packs containing 4 and 6 unit dose pipettes. Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

After use, replace cap on tube. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

### **7. MARKETING AUTHORISATION HOLDER**

*[to be completed nationally]*

### **8. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

### **10. DATE OF REVISION OF THE TEXT**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

### **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Outer carton, pack size of 4 and 6 pipettes – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 4.0 ml pipette contains:

Active substances: 400 mg imidacloprid, 2000 mg permethrin

**3. PHARMACEUTICAL FORM**

Spot-on solution

**4. PACKAGE SIZE**

4 pipettes (4x 4.0 ml)  
6 pipettes (6x 4.0 ml)

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

[For cartons: this text for front (only) of carton.]

- Eliminates ticks, fleas and biting lice
- Repels ticks, mosquitos, sand flies, and stable flies
- Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

[For cartons: this text for back (only) of carton]

- Eliminates fleas (treatment and prevention); can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and eliminates ticks; reducing the risk of transmission of CVBD (diseases such as borreliosis, rickettsiosis, and ehrlichiosis).
- Repels mosquitoes and sand flies; reducing the risk of transmission of leishmaniosis.
- Repels stable flies; contributing to the prevention of fly-bite dermatitis.

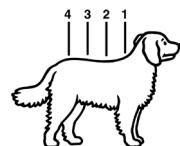
**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

**Read the package leaflet before use.**

Keep the foil pouch with the blisters in the outer carton.

[Dog Application –Pictogram (size specific corresponding to the product size)]



## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

**Read the package leaflet before use.**

Do not use on puppies of less than 7 weeks of age or 25 kg of weight.

**Do not use on cats.**

[Do Not Use on Cats -Pictogram]



## 10. EXPIRY DATE

Expiry/EXP {month/year}

Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.

## 11. SPECIAL STORAGE CONDITIONS

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

*[Prescription status to be completed nationally]*

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:

*[to be completed nationally]*

Distributed by:

*[to be completed nationally]*

**16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**17. MANUFACTURER'S BATCH NUMBER**

Batch No./Lot {number}



[Note: Depending on prevalent pests in CMSs, not all target pest pictograms may be used in every country]

[Figure of pipette, photo of dog]

Other Information:

- Remains effective if the dog becomes wet.
- Provides a larvicidal effect against fleas in the immediate surroundings of the treated dogs
- Can be used on both pregnant and lactating bitches.

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Outer carton, pack size of 4 and 6 pipettes – Product in long-neck tubes**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg

### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each 4.0 ml pipette contains:

Active substances: 400 mg imidacloprid, 2000 mg permethrin

### **3. PHARMACEUTICAL FORM**

Spot-on solution

### **4. PACKAGE SIZE**

4 pipettes (4x 4.0 ml)  
6 pipettes (6x 4.0 ml)

### **5. TARGET SPECIES**

Dogs

### **6. INDICATION(S)**

[For cartons: this text for front (only) of carton.]

- Eliminates ticks, fleas and biting lice
- Repels ticks, mosquitos, sand flies, and stable flies
- Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

[For cartons: this text for back (only) of carton]

- Eliminates fleas (treatment and prevention); can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and eliminates ticks; reducing the risk of transmission of CVBD (diseases such as borreliosis, rickettsiosis, and ehrlichiosis).
- Repels mosquitoes and sand flies; reducing the risk of transmission of leishmaniosis.
- Repels stable flies; contributing to the prevention of fly-bite dermatitis.

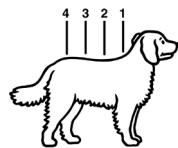
### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

**Read the package leaflet before use.**

Keep the foil pouch(es) in the outer carton.

[Dog Application –Pictogram (size specific corresponding to the product size)]



#### **8. WITHDRAWAL PERIOD(S)**

#### **9. SPECIAL WARNING(S), IF NECESSARY**

**Read the package leaflet before use.**

Do not use on puppies of less than 7 weeks of age or 25 kg of weight.

**Do not use on cats.**

[Do Not Use on Cats -Pictogram]



#### **10. EXPIRY DATE**

Expiry/EXP {month/year}

#### **11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

After opening the foil pouch the product must be applied to the dog's skin.

#### **12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

#### **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only

*[Prescription status to be completed nationally]*

#### **14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:  
*[to be completed nationally]*

Distributed by:  
*[to be completed nationally]*

**16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**17. MANUFACTURER'S BATCH NUMBER**

Batch No./Lot {number}



[Note: Depending on prevalent pests in CMSs, not all target pest pictograms may be used in every country]

[Figure of pipette, photo of dog]

Other Information:

- Remains effective if the dog becomes wet.
- Provides a larvicidal effect against fleas in the immediate surroundings of the treated dogs
- Can be used on both pregnant and lactating bitches.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Pipette label – international version (no translation required) – Product in short-neck tubes and long-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

100 mg/ml imidacloprid(e)

500 mg/ml permethrin(e)

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

4.0 ml

**4. ROUTE(S) OF ADMINISTRATION****5. WITHDRAWAL PERIOD(S)****6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size]



>25 kg ≤ 40 kg

[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister – international version (no translation required) – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

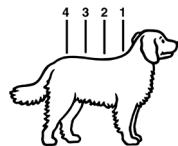
Distributed by [to be completed]

**3. EXPIRY DATE**

**4. BATCH NUMBER**

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]



>25 kg ≤ 40 kg

4.0 ml

[Tube-picto]



[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Foil pouch – international version (no further translation required) – Product in short-neck tubes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

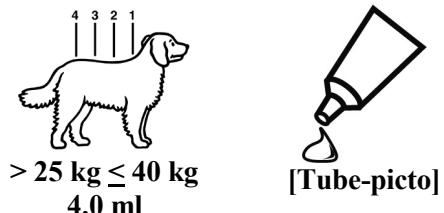
EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]

**FURTHER INFORMATION**

[Do Not Use on Cats -Pictogram]



Country code	
---	Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.
IT	Utilizzare entro 24 mesi dopo l'apertura della busta di alluminio o prima della data di scadenza (EXP) qualora sia più breve.
NL	Gebruiken binnen 24 maanden na opening van het zakje of vóór EXP, het kortste van de twee.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS****Foil pouch – international version (no further translation required) – Product in long-neck tubes****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

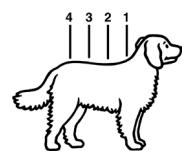
EXP {month/year}

**4. BATCH NUMBER**

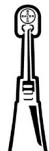
Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]



> 25 kg ≤ 40 kg  
4.0 ml



[Tube-picto]

**FURTHER INFORMATION**

[Do Not Use on Cats -Pictogram]



After opening the foil pouch the product must be applied to the dog's skin.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET [Product in short-neck tubes]**

**Petcuten™ Spot-on solution for Dogs**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder  
*[to be completed nationally]*

Distributed by:  
*[to be completed nationally]*

Manufacturer responsible for batch release  
KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs up to 4 kg  
Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg  
Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg  
Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg  
Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg

imidacloprid, permethrin

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each pipette contains:

	Pipette	Imidacloprid	Permethrin	N-Methylpyrrolidone	Butylhydroxytoluene (E321)
Petcuten™ Spot-on solution for dogs ≤ 4 kg	0.4 ml	40 mg	200 mg	194 mg	0.4 mg
Petcuten™ Spot-on solution for dogs > 4 ≤ 10 kg	1.0 ml	100 mg	500 mg	484 mg	1.0 mg
Petcuten™ Spot-on solution for dogs > 10 ≤ 25 kg	2.5 ml	250 mg	1250 mg	1210 mg	2.5 mg
Petcuten™ Spot-on solution for dogs > 25 kg ≤ 40 kg	4.0 ml	400 mg	2000 mg	1936 mg	4.0 mg
Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg	6.0 ml	600 mg	3000 mg	2904 mg	6.0 mg

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

A clear yellowish to brownish spot-on solution.

#### 4. INDICATIONS

For the treatment and prevention of flea (*C. canis*, *C. felis*) infestation and for the treatment of biting lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*P. papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*A. aegypti* for two weeks and *C. pipiens* for four weeks) and against stable flies (*S. calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

Sand flies	<i>P. perniciosus</i>	3 weeks
	<i>P. papatasi</i>	2 weeks
Mosquitoes	<i>A. aegypti</i>	2 weeks
	<i>C. pipiens</i>	4 weeks
Stable flies	<i>S. calcitrans</i>	4 weeks

#### 5. CONTRAINDICATIONS

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding Petcuten™ product must be used, see dosing scheme.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

#### 6. ADVERSE REACTIONS

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as

unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

### *Dosing Scheme*

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
4 kg and less	Petcuten™ Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
More than 4 to 10 kg	Petcuten™ Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
More than 10 to 25 kg	Petcuten™ Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
More than 25 to 40 kg	Petcuten™ Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
More than 40 to 60 kg	Petcuten™ Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

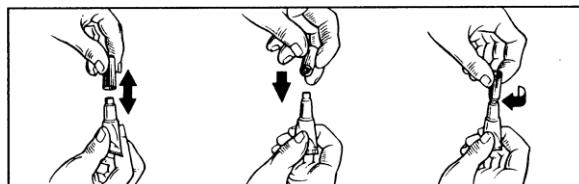
The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten™ or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

#### *Method of Administration*

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



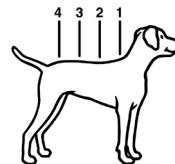
#### For dogs up to 10 kg body weight:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



#### For dogs over 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten™ pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin



## **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.

Apply only to undamaged skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

For 0.4 ml – 4.0 ml: Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.

For 6.0 ml: Use within 12 months after opening the foil pouch or before EXP, whichever is shorter.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch, or carton after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNINGS

### Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (diseases such as borrellosis, rickettsiosis, ehrlichiosis, leishmaniosis).

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

### Special precautions for use in animals:

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

The warning below only applies to products for dogs of more than 10 kg:

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

Other precautions:

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten™ Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:

The product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

Incompatibilities:

None known.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

After use, replace cap on tube. Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

### **15. OTHER INFORMATION**

Petcuten™ Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin containing products are toxic to honey bees.

Pack sizes: 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml and 6.0 ml per pipette; packs containing 4 and 6 single-use pipette packs.

Not all pack sizes may be marketed.

## PACKAGE LEAFLET [Product in long-neck tubes]

### Petcuten™ Spot-on solution for Dogs

#### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder  
[to be completed nationally]

Distributed by:  
[to be completed nationally]

Manufacturer responsible for batch release  
KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Petcuten™ Spot-on solution for dogs up to 4 kg  
Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg  
Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg  
Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg

imidaclorpid, permethrin

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each pipette contains:

	Pipette	Imidaclorpid	Permethrin	N-Methylpyrrolidone	Butylhydroxytoluene (E321)
Petcuten™ Spot-on solution for dogs ≤ 4 kg	0.4 ml	40 mg	200 mg	194 mg	0.4 mg
Petcuten™ Spot-on solution for dogs > 4 ≤ 10 kg	1.0 ml	100 mg	500 mg	484 mg	1.0 mg
Petcuten™ Spot-on solution for dogs > 10 ≤ 25 kg	2.5 ml	250 mg	1250 mg	1210 mg	2.5 mg
Petcuten™ Spot-on solution for dogs > 25 kg ≤ 40 kg	4.0 ml	400 mg	2000 mg	1936 mg	4.0 mg

A clear yellowish to brownish spot-on solution.

#### 4. INDICATIONS

For the treatment and prevention of flea (*C. canis*, *C. felis*) infestation and for the treatment of biting

lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*P. papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*A. aegypti* for two weeks and *C. pipiens* for four weeks) and against stable flies (*S. calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

Sand flies	<i>P. perniciosus</i>	3 weeks
	<i>P. papatasi</i>	2 weeks
Mosquitoes	<i>A. aegypti</i>	2 weeks
	<i>C. pipiens</i>	4 weeks
Stable flies	<i>S. calcitrans</i>	4 weeks

## 5. CONTRAINDICATIONS

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding Petcuten™ product must be used, see dosing scheme.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

## 6. ADVERSE REACTIONS

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

### *Dosing Scheme*

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
4 kg and less	Petcuten™ Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
More than 4 to 10 kg	Petcuten™ Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
More than 10 to 25 kg	Petcuten™ Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
More than 25 to 40 kg	Petcuten™ Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
More than 40 to 60 kg	Petcuten™ Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

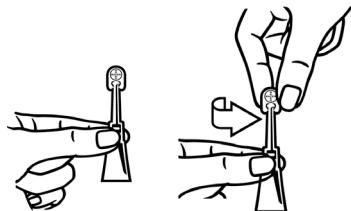
The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten™ or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

#### *Method of Administration*

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off.



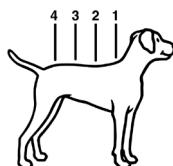
#### For dogs up to 10 kg body weight:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



#### For dogs over 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten™ pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin



### **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.

Apply only to undamaged skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

### **10. WITHDRAWAL PERIOD(S)**

Not applicable.

### **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not freeze.

After opening the foil pouch the product must be applied to the dog's skin.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch, or carton after EXP. The expiry date refers to the last day of that month.

## **12. SPECIAL WARNINGS**

### Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (diseases such as borreliosis, rickettsiosis, ehrlichiosis, leishmaniosis).

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

### Special precautions for use in animals:

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

The warning below only applies to products for dogs of more than 10 kg:

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

#### Other precautions:

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten™ Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

#### Pregnancy and lactation:

The product can be used during pregnancy and lactation.

#### Interaction with other medicinal products and other forms of interaction:

None known.

#### Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

#### Incompatibilities:

None known.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

After use, replace cap on tube. Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

## **15. OTHER INFORMATION**

Petcuten™ Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin containing products are toxic to honey bees.

Pack sizes: 0.4 ml, 1.0 ml, 2.5 ml and 4.0 ml per pipette; packs containing 4 and 6 single-use pipette packs.

Not all pack sizes may be marketed.

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Petcuten Spot-on solution for dogs over 40 kg up to 60 kg

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 6.0 ml contains:

### **Active substances:**

Imidacloprid: 600.0 mg  
Permethrin (40/60): 3000.0 mg

### **Excipient(s):**

N-Methylpyrrolidone: 2904 mg  
Butylhydroxytoluene (E321): 6.0 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Spot-on solution

Clear yellowish to brownish solution

## 4. CLINICAL PARTICULARS

### **4.1 Target species**

Dogs (over 40 kg up to 60 kg)

For dogs less than or equal to 40 kg or more than 60 kg body weight, use the appropriate Petcuten Spot-on solution product or combination of products (see section 4.9).

### **4.2 Indications for use, specifying the target species**

For the treatment and prevention of flea (*Ctenocephalides canis*, *Ctenocephalides felis*) infestation.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

For the treatment of biting lice (*Trichodectes canis*).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks) and against stable flies (*Stomoxys calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

#### **4.3 Contraindications**

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 40 kg of weight.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats. (Refer to section 4.5 – Special precautions for use).

#### **4.4 Special warnings for each target species**

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

#### **4.5 Special precautions for use**

##### **i) Special precautions for use in animals**

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under section 4.9. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

**ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

**iii) Other precautions**

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

**4.6 Adverse reactions (frequency and seriousness)**

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

#### 4.8 Interaction with other medicinal products and other forms of interaction

None known.

#### 4.9 Amounts to be administered and administration route

For dermal use only. Apply only to undamaged skin.

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

*Dosing Scheme for Petcuten Spot-on:*

Dogs (kg body weight)	Trade name	Volume (ml)	Imidacloprid (mg/kg body weight)	Permethrin (mg/kg body weight)
≤ 4 kg	Petcuten Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
>4 kg ≤ 10 kg	Petcuten Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
>10 kg ≤ 25 kg	Petcuten Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
>25 kg ≤ 40 kg	Petcuten Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
>40 kg ≤ 60 kg	Petcuten Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50- 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

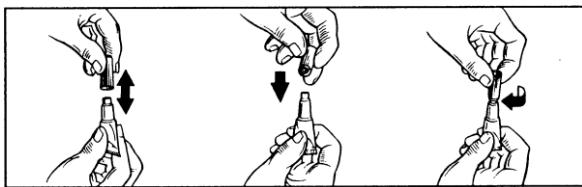
To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should be administered before applying Petcuten or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



With the dog standing still, the entire contents of the Petcuten pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.



#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

#### 4.11 Withdrawal period(s)

Not applicable.

### 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic agent,  
ATC vet code: QP53AC54

Petcuten Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

#### 5.1 Pharmacodynamic properties

**Imidacloprid** is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it can be classified as a chloronicotinyl nitroguanidine. Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal. It has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) in insects. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death of the parasite.

**Permethrin** belongs to the type I class of pyrethroid acaricides and insecticides and also acts as repellent. Pyrethroids affect the voltage-gated sodium channels in vertebrates and non-vertebrates. Pyrethroids are so called "open channel blockers" affecting the sodium channel by slowing both the activation and the inactivation properties thus leading to hyperexcitability and death of the parasite.

In the combination of both substances, it has been shown Imidacloprid functions as the activator of arthropod ganglion and therefore increases the efficacy of permethrin.

The product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (e.g. borrellosis, rickettsiosis, ehrlichiosis, leishmaniosis). However, there may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. The product provides repellent (anti-feeding) activity against stable flies thereby assisting in the prevention of fly-bite dermatitis.

The product provides repellent activity (anti-feeding activity) against *Phlebotomus perniciosus* (> 80% for 3 weeks), mosquitoes and ticks. Field data from an endemic area showed that the product indirectly reduces the risk of transmission of *Leishmania infantum* from infected sandflies (*Phlebotomus perniciosus*) for up to 3 weeks, thereby reducing the risk of canine leishmaniosis in treated dogs.

## 5.2 Pharmacokinetic particulars

The product is indicated for dermal administration. Following topical application in dogs, the solution rapidly distributes over the body surface of the animal. Both active substances remain detectable on the skin and hair of the treated animal for 4 weeks.

Acute dermal studies in the rat and target animal, overdose and serum kinetic studies have established that systemic absorption of both active substances after application on intact skin is low, transient and not relevant for the clinical efficacy.

## 5.3 Environmental properties

The product should not be allowed to enter water courses as this may be dangerous for fish and aquatic organisms. For treated dogs, please see section 4.5.

Permethrin containing products are toxic to honey bees.

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Butylhydroxytoluene (E321)  
N-Methylpyrrolidone  
Triglycerides, medium-chain  
Citric acid (E330; for pH adjustment)

## 6.2 Major incompatibilities

None known.

## 6.3 Shelf life

Shelf-life of product in foil pouch:	3 years.
Shelf life of product after opening foil pouch:	12 months (all pipettes should be used within 12 months after opening the foil pouch or before expiry date on the pipette whichever is shorter).
Shelf-life of the broached pipette:	Once opened, the entire contents of the pipette has to be applied to the animal's skin.

#### **6.4. Special precautions for storage**

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

#### **6.5 Nature and composition of immediate packaging**

Fill volume: 6.0 ml

Type of the container: White polypropylene pipette.  
White polypropylene cap.

Material of the secondary packaging: Polychlorotrifluoroethylene PCTFE/PVC or PVC heat sealed blister packs in one or more aluminium pouch(es) and a cardboard box.

Package sizes: Packs containing 4 and 6 unit dose pipettes. Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

After use, replace cap on tube. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

### **7. MARKETING AUTHORISATION HOLDER**

*[to be completed nationally]*

### **8. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

### **10. DATE OF REVISION OF THE TEXT**

*[to be completed in accordance with national requirements after conclusion of the MR phase]*

### **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**outer carton, pack size of 4 and 6 pipettes**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each 6.0 ml pipette contains:

Active substances: 600 mg imidacloprid, 3000 mg permethrin

**3. PHARMACEUTICAL FORM**

Spot-on solution

**4. PACKAGE SIZE**

4 pipettes (4x 6.0ml)

**6 pipettes (6x 6.0ml)**

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)**

[For cartons: this text for front (only) of carton.]

- Eliminates ticks, fleas and biting lice
- Repels ticks, mosquitos, sand flies, and stable flies
- Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

[For cartons: this text for back (only) of carton]

- Eliminates fleas (treatment and prevention); can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and eliminates ticks; reducing the risk of transmission of CVBD (diseases such as borreliosis, rickettsiosis, and ehrlichiosis).
- Repels mosquitoes and sand flies; reducing the risk of transmission of leishmaniosis.
- Repels stable flies; contributing to the prevention of fly-bite dermatitis.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

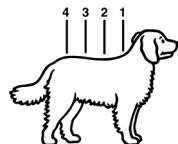
For external use only.

One pipette for dogs weighing over 40 to 60 kg.

**Read the package leaflet before use.**

Keep the foil pouch with the blisters in the outer carton.

[Dog Application –Pictogram (size specific corresponding to the product size)]



## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

**Read the package leaflet before use.**

Do not use on puppies of less than 7 weeks of age or 40 kg of weight.

**Do not use on cats.**

[Do Not Use on Cats -Pictogram]



## 10. EXPIRY DATE

EXP {month/year}

Use within 12 months after opening the foil pouch or before EXP, whichever is shorter.

## 11. SPECIAL STORAGE CONDITIONS

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

*[Prescription status to be completed nationally]*

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder:  
*[to be completed nationally]*

Distributed by:  
*[to be completed nationally]*

**16. MARKETING AUTHORISATION NUMBER(S)**

*[to be completed nationally]*

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}



[Note: Depending on prevalent pests in CMSs, not all target pest pictograms may be used in every country]

[Figure of pipette, photo of dog]

Other Information:

- Remains effective if the dog becomes wet.
- Provides a larvicidal effect against fleas in the immediate surroundings of the treated dogs
- Can be used on both pregnant and lactating bitches.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Pipette label – international version (no translation required)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

100 mg/ml imidacloprid(e)

500 mg/ml permethrin(e)

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

6.0 ml

**4. ROUTE(S) OF ADMINISTRATION**

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

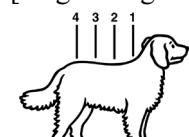
Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size]



>40 kg ≤ 60 kg

[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister – international version (no translation required)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

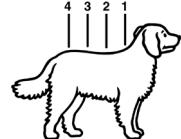
Distributed by [to be completed]

**3. EXPIRY DATE**

**4. BATCH NUMBER**

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]



>40 kg ≤ 60 kg

6.0 ml

[Tube-picto]



[Do Not Use on Cats -Pictogram]



**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**foil pouch – international version (no further translation required)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Distributed by [to be completed]

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

[Dog-Pictogram – Size specific corresponding to the product size – to be printed in black and white]



> 40 kg ≤ 60 kg

6.0 ml

[Tube-picto]



**FURTHER INFORMATION**

[Do Not Use on Cats -Pictogram]



Country code	
---	Use within 12 months after opening the foil pouch or before EXP, whichever is shorter.
IT	Utilizzare entro 12 mesi dopo l'apertura della busta di alluminio o prima della data di scadenza (EXP) qualora sia più breve.
NL	Gebruiken binnen 12 maanden na opening van het zakje of vóór EXP, het kortste van de twee.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET [Product in short-neck tubes]**

**Petcuten™ Spot-on solution for Dogs**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder  
[to be completed nationally]

Distributed by:  
[to be completed nationally]

Manufacturer responsible for batch release  
KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Petcuten™ Spot-on solution for dogs up to 4 kg  
Petcuten™ Spot-on solution for dogs over 4 kg up to 10 kg  
Petcuten™ Spot-on solution for dogs over 10 kg up to 25 kg  
Petcuten™ Spot-on solution for dogs over 25 kg up to 40 kg  
Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg

imidacloprid, permethrin

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Each pipette contains:

	Pipette	Imidacloprid	Permethrin	N-Methylpyrrolidone	Butylhydroxytoluene (E321)
Petcuten™ Spot-on solution for dogs ≤ 4 kg	0.4 ml	40 mg	200 mg	194 mg	0.4 mg
Petcuten™ Spot-on solution for dogs > 4 ≤ 10 kg	1.0 ml	100 mg	500 mg	484 mg	1.0 mg
Petcuten™ Spot-on solution for dogs > 10 ≤ 25 kg	2.5 ml	250 mg	1250 mg	1210 mg	2.5 mg
Petcuten™ Spot-on solution for dogs > 25 kg ≤ 40 kg	4.0 ml	400 mg	2000 mg	1936 mg	4.0 mg
Petcuten™ Spot-on solution for dogs over 40 kg up to 60 kg	6.0 ml	600 mg	3000 mg	2904 mg	6.0 mg

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

A clear yellowish to brownish spot-on solution.

## 4. INDICATIONS

For the treatment and prevention of flea (*C. canis*, *C. felis*) infestation and for the treatment of biting lice (*Trichodectes canis*) on dogs.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

The product has persistent acaricidal and repellent efficacy against tick infestations (*Rhipicephalus sanguineus* and *Ixodes ricinus* for four weeks, and *Dermacentor reticulatus* for three weeks).

By repelling and killing the tick vector *Rhipicephalus sanguineus*, the product reduces the likelihood of transmission of the pathogen *Ehrlichia canis*, thereby reducing the risk of canine ehrlichiosis. The reduction in risk has been shown in studies to commence from 3 days following application of the product and to persist for 4 weeks.

Ticks already on the dog may not be killed within two days after treatment and may remain attached and visible. Therefore the removal of ticks already on the dog at the time of treatment is recommended, in order to prevent them from attaching and having a blood meal.

One treatment provides repellent (anti-feeding) activity against sand flies (*P. papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks), against mosquitoes (*A. aegypti* for two weeks and *C. pipiens* for four weeks) and against stable flies (*S. calcitrans*) for four weeks.

Reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies (*Phlebotomus perniciosus*) for up to 3 weeks. The effect is indirect due to product's activity against the vector.

Sand flies	<i>P. perniciosus</i>	3 weeks
	<i>P. papatasi</i>	2 weeks
Mosquitoes	<i>A. aegypti</i>	2 weeks
	<i>C. pipiens</i>	4 weeks
Stable flies	<i>S. calcitrans</i>	4 weeks

## 5. CONTRAINDICATIONS

In the absence of available data the product should not be used on puppies of less than 7 weeks of age or 1.5 kg of weight. According to the dog's body weight the corresponding Petcuten™ product must be used, see dosing scheme.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on cats.

## 6. ADVERSE REACTIONS

Application site itching and hair change (e.g. greasy fur) and vomiting were uncommonly observed in clinical studies. Other reactions like redness, inflammation and hair loss at the application site and diarrhea were reported rarely.

On very rare occasions reactions in dogs including transient skin sensitivity (scratching and rubbing) or lethargy were reported in spontaneous (pharmacovigilance) reports. These reactions are generally self-resolving.

In very rare cases dogs may show behaviour changes (agitation, restlessness, whining or rolling), gastro-intestinal symptoms (hypersalivation, diminished appetite) and neurological signs such as unsteady movement and twitching in dogs susceptible to the ingredient permethrin. These signs are generally transient and self-resolving.

Poisoning following inadvertent oral uptake in dogs is unlikely but may occur in very rare cases. In this event, neurological signs such as tremor and lethargy can occur. Treatment should be symptomatic. There is no known specific antidote.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended minimum dose is:

10 mg/kg body weight (bw) imidacloprid and 50 mg/kg body weight (bw) permethrin.

### *Dosing Scheme*

Dogs (kg bw)	Trade name	Volume (ml)	Imidacloprid (mg/kg bw)	Permethrin (mg/kg bw)
4 kg and less	Petcuten™ Spot-on for dogs up to 4 kg	0.4 ml	minimum of 10	minimum of 50
More than 4 to 10 kg	Petcuten™ Spot-on for dogs over 4 kg up to 10 kg	1.0 ml	10 - 25	50 - 125
More than 10 to 25 kg	Petcuten™ Spot-on for dogs over 10 kg up to 25 kg	2.5 ml	10 - 25	50 - 125
More than 25 to 40 kg	Petcuten™ Spot-on for dogs over 25 kg up to 40 kg	4.0 ml	10 - 16	50 - 80
More than 40 to 60 kg	Petcuten™ Spot-on for dogs over 40 kg up to 60 kg	6.0 ml	10 - 15	50 - 75

For dogs > 60 kg the appropriate combination with other sized pipettes should be used.

To reduce re-infestation from emergence of new fleas, it is recommended to treat all dogs in a household. Other animals living in the same household should also be treated with a suitable product. To aid further in reducing environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developmental stages is recommended.

The product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. In cases of frequent water exposure the persistent efficacy may be reduced. In these cases do not retreat more frequently than once weekly. If a dog requires a shampoo, it should

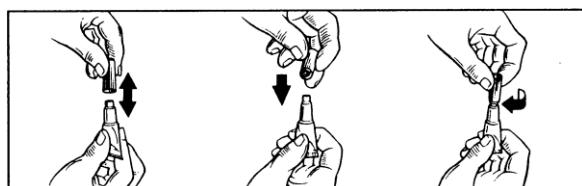
be administered before applying Petcuten™ or at least 2 weeks after application, to optimise efficacy of the product.

In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

To protect a dog over the whole sand fly season, treatment should be compliantly continued throughout.

#### *Method of Administration*

Remove one pipette from the package. Hold applicator pipette in an upright position, twist and pull cap off. Turn the cap around and place the other end of cap back on pipette. Twist cap to break seal, then remove cap from pipette.



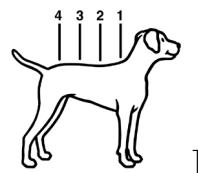
#### For dogs up to 10 kg body weight:

With the dog standing still, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



#### For dogs over 10 kg body weight:

With the dog standing still, the entire contents of the Petcuten™ pipette should be applied evenly to four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the solution on the skin



## **9. ADVICE ON CORRECT ADMINISTRATION**

For external use only.

Apply only to undamaged skin.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not freeze.

After opening the foil pouch store in a dry place at a temperature not above 30°C.

For 0.4 ml – 4.0 ml: Use within 24 months after opening the foil pouch or before EXP, whichever is shorter.

For 6.0 ml: Use within 12 months after opening the foil pouch or before EXP, whichever is shorter.

Do not use this veterinary medicinal product after the expiry date which is stated on the pipette, foil pouch, or carton after EXP. The expiry date refers to the last day of that month.

## **12. SPECIAL WARNINGS**

### Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand flies or mosquitoes. For this reason, a transmission of infectious diseases by these parasites cannot be completely excluded if conditions are unfavourable. However, the product provides repellent (anti-feeding) activity against ticks, sand flies and mosquitoes, thus preventing the repelled parasites from taking a blood meal and thus reducing the risk of Canine Vector-Borne Disease (CVBD) transmission (diseases such as borreliosis, rickettsiosis, ehrlichiosis, leishmaniosis).

Immediate protection against sandflies bites is not documented. Treated dogs for the reduction of the risk of infection with *Leishmania infantum* via transmission by sandflies *P. perniciosus* should be kept in a protected environment during the first 24 hours after the initial treatment application.

It is recommended to apply the treatment at least 3 days before expected exposure to *E. canis*. With regard to *E. canis*, studies have demonstrated a reduced risk of canine ehrlichiosis in dogs exposed to *Rhipicephalus sanguineus* ticks infected with *E. canis* from 3 days following application of the product and to persist for 4 weeks.

### Special precautions for use in animals

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs.

Care should be taken to administer the product correctly as described under *Method of Administration*. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

Do not use on cats.



This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise certain compounds including permethrin. To prevent cats from being

accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry. It is important to ensure that cats do not groom the site of application on a dog, which has been treated with this product. Seek veterinary advice immediately if this occurs.

Consult your veterinary surgeon before using the product on sick and debilitated dogs.

**Special precautions to be taken by the person administering the veterinary medicinal product to animals:**

Avoid contact between the product and skin, eyes or mouth.

Do not eat, drink or smoke during application.

Wash hands thoroughly after use.

In case of accidental spillage onto skin, wash off immediately with soap and water.

People with known skin sensitivity may be particularly sensitive to this product.

The predominant clinical symptoms that in extremely rare case may be shown are transient sensory irritations of the skin like tingling, burning sensation or numbness.

If the product gets accidentally into the eyes, they should be thoroughly flushed with water. If skin or if eye irritation persists obtain medical attention immediately and show the package insert to the physician.

Do not ingest. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

Treated dogs should not be handled especially by children until the application site is dry. This may be ensured by treating the dogs e.g. in the evening. Recently treated dogs should not be allowed to sleep together with their owner, especially children.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

The warning below only applies to products for dogs of more than 10 kg:

Laboratory studies in rabbits and rats with the excipient N-Methylpyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

**Other precautions:**

As the product is dangerous to aquatic organisms, treated dogs must not under any circumstances be allowed into any type of surface water for at least 48 hours after treatment.

The solvent in Petcuten™ Spot-on solution may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

**Pregnancy and lactation:**

The product can be used during pregnancy and lactation.

**Interaction with other medicinal products and other forms of interaction:**

None known.

**Overdose (symptoms, emergency procedures, antidotes):**

No adverse clinical signs were noted in healthy puppies or adult dogs exposed to 5x overdosage or for puppies whose mothers were treated with 3x overdosage of the product.

Incompatibilities:

None known.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

After use, replace cap on tube. Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

Petcuten™ Spot-on is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

Imidacloprid is effective against adult fleas and larval flea stages. In addition to the adulticide flea efficacy of imidacloprid, a larvical flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the dog's immediate surroundings are killed following contact with a treated animal.

Permethrin containing products are toxic to honey bees.

Pack sizes: 0.4 ml, 1.0 ml, 2.5 ml, 4.0 ml and 6.0 ml per pipette; packs containing 4 and 6 single-use pipette packs.

Not all pack sizes may be marketed.