

*[Version 9.1, 11/2024]*

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage 400 mg spot-on solution for dogs ( $\geq 25$  kg)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.0 ml unit dose (pipette) contains:

### Active substance:

Imidacloprid 400 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E1519)	
Propylene carbonate	
Butylhydroxytoluene (E321)	1.0 mg/ml

Clear yellow to slightly brownish solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs.

### 3.2 Indications for use for each target species

For the prevention and treatment of flea infestations and for the treatment of biting lice (*Trichodectes canis*). Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

### 3.3 Contraindications

Do not treat unweaned puppies of less than 8 weeks of age.

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

### 3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with fleas and biting lice should be considered, and these should be treated as necessary with an appropriate product.

Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid reduction in environmental challenge, the additional use

of a suitable environmental treatment against adult fleas and their developing stages is recommended, especially of the animal's basket, bedding and regular resting areas such as carpets and soft furnishings. In order to reduce further the environmental challenge, it is recommended that all dogs in the household are treated. Treatment of nursing bitches controls flea infestations on both dam and offspring.

The veterinary medicinal product remains effective if the animal becomes wet, for example after swimming or exposure to heavy rain. However, in cases of frequent swimming or bathing re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not treat more frequently than once weekly.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

This veterinary medicinal product is for topical use and should not be administered orally. Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.  
Do not allow recently treated animals to groom each other.

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

This veterinary medicinal product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling). People with known hypersensitivity to imidacloprid and benzyl alcohol should avoid contact with the veterinary medicinal product.

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

Do not massage the application site.

Do not eat, drink or smoke during application.

Wash off any skin contamination with soap and water.

If the veterinary medicinal product gets into eyes accidentally, the eyes should be thoroughly flushed with water. If skin or eye irritation persists, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.

After application, do not stroke or groom animals until application site is dry.

Wash hands thoroughly after use.

#### Special precautions for the protection of the environment:

Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter surface water for 48 hours after treatment. See also section 5.5.

#### Other precautions:

The solvent in this veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

### 3.6 Adverse events

Dogs:

Very rare ( $<1$ animal / 10 000 animals treated, including isolated reports):	Agitation Hypersalivation <sup>1</sup> Disorientation, Neurological signs (e.g. Depression, Incoordination, Tremor)
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	Application site reaction (e.g. Hair loss, Itching, Reddening of the skin, Skin lesion)
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<sup>1</sup>May occur if the dog licks the application site immediately after treatment due to the bitter taste. This is not a sign of intoxication and disappears within some minutes without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

#### Pregnancy and lactation:

No primary embryotoxic, teratogenic or reproductive toxic effects have been observed during the studies with imidacloprid on rats and rabbits.

Studies on pregnant and lactating bitches together with their offspring are limited. Evidence so far suggests that no adverse effects are to be expected in these animals.

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

No incompatibility has been observed between this veterinary medicinal product at twice the recommended dose and the following commonly used veterinary medicinal products: fenthion, lufenuron, milbemycin, febantel, pyrantel and praziquantel. The compatibility of the veterinary medicinal product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

### 3.9 Administration routes and dosage

Spot-on use. For external use only.

Underdosing could result in ineffective use and may favour resistance development. To ensure a correct dosage, body weight should be determined as accurately as possible.

#### *Dosage and treatment schedule:*

The recommended minimum dose is 10 mg imidacloprid per kg body weight (bw), equivalent to 0.1 ml/kg bw of the veterinary medicinal product.

Dog weight (kg)	Pipette size to be used	Pipette volume (ml)	Imidacloprid (mg/kg bw)
≥25 - <40 kg	Advantage 400 mg for dogs	4.0	minimum of 10
≥40 kg	Use the appropriate combination of pipettes		minimum of 10

For dogs smaller 25 kg bw, use an appropriate available pipette size to achieve the recommended dose for the weight of the animal to be treated.

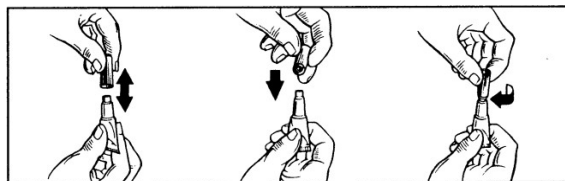
For dogs of more than 40 kg bw, use an appropriate combination of available pipette sizes to achieve the recommended minimum dose of 10 mg/kg bw.

For treatment or prevention of infestations with the parasites indicated for use of this veterinary medicinal product, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

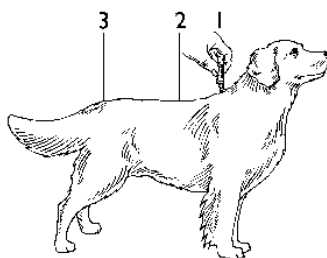
In case of biting louse infestation, a further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

#### *Method of administration:*

Remove one pipette from the package. For dogs of 40 kg body weight and greater use two pipettes. Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.



The dog should be standing for easy application. The entire contents of the pipette(s) should be applied evenly to three or four spots all located at different application sites along the dog's backline from the shoulder to the base of the tail. At each spot part the coat until the skin is visible.



Place the tip of the pipette on the skin and gently squeeze to expel a portion of the contents directly onto 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. Correct application will minimize the opportunity for the dog to lick the veterinary medicinal product. Apply only to undamaged skin.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

No adverse clinical signs were produced by either individual doses of up to 200 mg/kg body weight (five to eight times the therapeutic dose), daily treatments at 100 mg/kg body weight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks.

In rare cases of overdose or licking of treated fur, nervous system disorders (such as twitching, tremors, ataxia, mydriasis, miosis, lethargy) can occur.

Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 Withdrawal periods**

Not applicable.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code : QP53AX17**

## **4.2 Pharmacodynamics**

Imidacloprid, 1-(6-Chloro-3-pyridylmethyl)-N-nitro-imidazolidin-2-ylideneamine is an ectoparasiticide belonging to a group of chloronicotinyl compounds. Chemically, it is more accurately described as a chloronicotinyl nitroguanidine.

The substance has a high affinity for the nicotinergeric acetylcholine receptors in the post-synaptic region of the central nervous system (CNS). The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinergeric receptor sites and the postulated poor penetration through the blood/brain barrier in mammals, it has virtually no effect on the mammalian CNS. The minimal pharmacological activity in mammals is supported by safety studies involving systemic administration of sub-lethal doses to rabbits, mice and rats.

In further studies, 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 pet's surroundings are killed following contact with a treated animal.

## **4.3 Pharmacokinetics**

The veterinary medicinal product is indicated for cutaneous administration. Following topical application in dogs, the solution is quickly distributed over the animal. Acute dermal studies in the rat and target animal overdose and serum kinetic studies have established that systemic absorption is very low, transient and not relevant for the clinical efficacy. This has been further demonstrated by a study in which fleas were not killed after having fed on previously treated animals once the animal's skin and fur had been cleaned of all active material.

# **5. PHARMACEUTICAL PARTICULARS**

## **5.1 Major incompatibilities**

None known.

## **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

## **5.3 Special precautions for storage**

This veterinary medicinal product does not require any special storage conditions. Keep the blister in the outer carton.

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

White polypropylene unit dose pipette closed with white polypropylene screw cap. Unit dose pipettes are packed in polyvinyl chloride and aluminium foil blisters.

Pack sizes:

Cardboard box containing a total of 1, 2, 3, 4 or 6 unit dose pipettes in a blister sheet. Each unit dose pipette contains 4.0 ml of solution.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as imidacloprid may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

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

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

**8. DATE OF FIRST AUTHORISATION**

{DD month YYYY}

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

{MM/ YYYY}

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription. (IE)

Veterinary medicinal product not subject to prescription. (AT, DE, DK, ES, IT, NL, UK(NI))

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**



## **A. LABELLING**

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

### CARDBOARD BOX

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

Advantage 400 mg spot-on solution

#### 2. STATEMENT OF ACTIVE SUBSTANCES

Each 4.0 ml pipette contains: 400 mg imidacloprid

#### 3. PACKAGE SIZE

1 pipette  
2 pipettes  
3 pipettes  
4 pipettes  
6 pipettes

#### 4. TARGET SPECIES



≥25 kg

#### 5. INDICATIONS

For veterinary medicinal products not subject to veterinary prescription:

Flea prevention and flea and biting louse (*Trichodectes canis*) treatment.

Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

[Pictograms]



Flea



Louse

#### 6. ROUTES OF ADMINISTRATION

Spot-on use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

Keep the blister in the outer carton.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.


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

For animal treatment only.

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

Keep out of the sight and reach of children.

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

Elanco 

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

<b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</b> <b>BLISTER</b>
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<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
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Advantage



≥25 kg

<b>2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES</b>
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400 mg imidacloprid

4.0 ml

<b>3. BATCH NUMBER</b>
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Lot {number}

<b>4. EXPIRY DATE</b>
-----------------------

Exp. {mm/yyyy}

<b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</b> <b>PIPETTE LABEL</b>
---

<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
--

Advantage



≥25 kg

<b>2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES</b>
---

4.0 ml

<b>3. BATCH NUMBER</b>
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Lot {number}

<b>4. EXPIRY DATE</b>
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Exp. {mm/yyyy}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Advantage 40 mg spot-on solution for dogs (<4 kg)  
Advantage 100 mg spot-on solution for dogs (≥4 - <10 kg)  
Advantage 250 mg spot-on solution for dogs (≥10 - <25 kg)  
Advantage 400 mg spot-on solution for dogs (≥25 kg)

### 2. Composition

Each unit dose (pipette) contains:

	Unit Dose	Imidacloprid
Advantage 40 mg for dogs (<4 kg)	0.4 ml	40 mg
Advantage 100 mg for dogs (≥4 - <10 kg)	1.0 ml	100 mg
Advantage 250 mg for dogs (≥10 - <25 kg)	2.5 ml	250 mg
Advantage 400 mg for dogs (≥25 kg)	4.0 ml	400 mg

### Excipients:

1.0 mg/ml butylhydroxytoluene (E321)

Clear yellow to slightly brownish solution.

### 3. Target species

Dogs.



### 4. Indications for use

For the prevention and treatment of flea infestations and for the treatment of biting lice (*Trichodectes canis*). Fleas on dogs are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD) where this has been previously diagnosed by a veterinary surgeon.

### 5. Contraindications

Do not treat unweaned puppies of less than 8 weeks of age.  
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

### 6. Special warnings

Special warnings:

Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with fleas and biting lice should be considered, and these should be treated as necessary with an appropriate product.

Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended, especially of the animal's basket, bedding and regular resting areas such as carpets and soft furnishings. In order to reduce further the environmental challenge, it is recommended that all dogs in the household are treated. Treatment of nursing bitches controls flea infestations on both dam and offspring.

The veterinary medicinal product remains effective if the animal becomes wet, for example after swimming or exposure to heavy rain. However, in cases of frequent swimming or bathing re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not treat more frequently than once weekly.

#### Special precautions for safe use in the target species:

This veterinary medicinal product is for topical use and should not be administered orally. Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.

Do not allow recently treated animals to groom each other.

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

This veterinary medicinal product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling). People with known hypersensitivity to imidacloprid and benzyl alcohol should avoid contact with the veterinary medicinal product.

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

Do not massage the application site.

Do not eat, drink or smoke during application.

Wash off any skin contamination with soap and water.

If the veterinary medicinal product gets into eyes accidentally, the eyes should be thoroughly flushed with water. If skin or eye irritation persists, or the veterinary medicinal product is accidentally swallowed, seek medical advice immediately and show the package leaflet or the label to the physician.

After application, do not stroke or groom animals until application site is dry.

Wash hands thoroughly after use.

#### Special precautions for the protection of the environment:

Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter surface water for 48 hours after treatment. See also section 'Special precautions for disposal'.

#### Other precautions:



The solvent in this veterinary medicinal product 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:

No primary embryotoxic, teratogenic or reproductive toxic effects have been observed during the studies with imidacloprid on rats and rabbits.

Studies on pregnant and lactating bitches together with their offspring are limited. Evidence so far suggests that no adverse effects are to be expected in these animals.

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

No incompatibility has been observed between this veterinary medicinal product at twice the recommended dose and the following commonly used veterinary medicinal products: fenthion, lufenuron, milbemycin, febantel, pyrantel and praziquantel. The compatibility of the veterinary medicinal product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

#### Overdose:

No adverse clinical signs were produced by either individual doses of up to 200 mg/kg body weight (five to eight times the therapeutic dose), daily treatments at 100 mg/kg body weight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks.

In rare cases of overdose or licking of treated fur, nervous system disorders (such as twitching, tremors, ataxia, mydriasis, miosis, lethargy) can occur.

Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

## **7. Adverse events**

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Agitation (hyperactivity) Hypersalivation <sup>1</sup> (drooling) Disorientation (confusion), Neurological signs (e.g. Depression (lethargy), Incoordination, Tremor) Application site reaction (e.g. Hair loss, Itching, Reddening of the skin, Skin lesion)

<sup>1</sup>May occur if the dog licks the application site immediately after treatment due to the bitter taste. This is not a sign of intoxication and disappears within some minutes without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## **8. Dosage for each species, routes and method of administration**

Spot-on use. For external use only.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Any instructions given by a veterinary surgeon for the use of this veterinary medicinal product should be followed.

*Dosage and treatment schedule:*

The recommended minimum dose is 10 mg imidacloprid per kg body weight (bw), equivalent to 0.1 ml/kg bw of the veterinary medicinal product.

Dog weight (kg)	Pipette size to be used	Pipette volume (ml)	Imidacloprid (mg/kg bw)
<4 kg	Advantage 40 mg for dogs	0.4	minimum of 10
≥4 - <10 kg	Advantage 100 mg for dogs	1.0	minimum of 10
≥10 - <25 kg	Advantage 250 mg for dogs	2.5	minimum of 10
≥25 - <40 kg	Advantage 400 mg for dogs	4.0	minimum of 10
≥40 kg	Use the appropriate combination of pipettes		minimum of 10

Select the appropriate pipette size for the weight of the animal to be treated.

For treatment or prevention of infestations with the parasites indicated for use of this veterinary medicinal product, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

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

## **9. Advice on correct administration**

Remove one pipette from the package. For dogs of 40 kg body weight and greater use the appropriate combination of pipettes. Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette as shown in figure 1.

### For dogs less than 25 kg body weight:

With the dog in the standing position, 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 as shown in figure 2.

### For dogs of 25 kg body weight and greater:

The dog should be standing for easy application. The entire contents of the pipette(s) should be applied evenly to three or four spots all located at different application sites along the dog's backline from the shoulder to the base of the tail as shown in figure 3.

At each spot part the coat until the skin is visible. Place the tip of the pipette on the skin and gently squeeze to expel a portion of the contents directly onto the skin.

### For all dogs:

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. Correct application will minimize the opportunity for the dog to lick the veterinary medicinal product. Apply only to undamaged skin.

### **For monolingual packaging only:**

Figures are shown below.

### **For multilingual packaging only:**

Figures are shown at the end of the leaflet.

*In order to facilitate multilingual package leaflets, figures were numbered, and this text added so that graphics can be printed only once at the end of the leaflet for multilingual leaflets.*

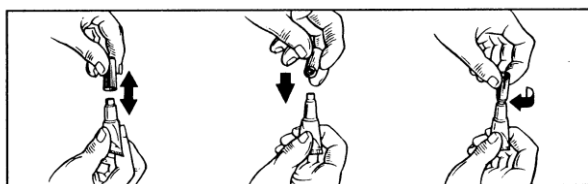


Figure 1



Figure 2

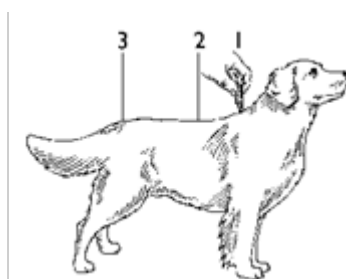


Figure 3

#### **10. Withdrawal periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Keep the blister in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and pipette after Exp. The expiry date refers to the last day of that month.

#### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as imidacloprid may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

**13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription. (IE)

Veterinary medicinal product not subject to prescription. (AT, DE, DK, ES, IT, NL, UK(NI))

**14. Marketing authorisation numbers and pack sizes**

Cardboard box containing a total of 1, 2, 3, 4 or 6 unit dose pipettes in a blister sheet.

Each unit dose pipette contains 0.4, 1.0, 2.5 or 4.0 ml of solution. Not all pack sizes may be marketed.

**15. Date on which the package leaflet was last revised**

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

**16. Contact details**

Marketing authorisation holder< and contact details to report suspected adverse events>:

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

Local representatives< and contact details to report suspected adverse events>:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**17. Other information**

In further studies, 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 pet's surroundings are killed following contact with a treated animal.