[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PrevenTix 250 mg/1250 mg spot-on solution for dogs over 10 kg up to 25 kg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2.5 ml pipette contains:

Active substances:

Imidacloprid	250.0 mg
Permethrin	1250.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxytoluene (E321)	2.5 mg
N-methyl pyrrolidone	1170 mg
Triglycerides, medium-chain	
Citric acid (E330)	

Clear yellowish spot-on solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (over 10 kg up to 25 kg).

3.2 Indications for use for each 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 veterinary medicinal product can be used as a part of a treatment strategy for flea allergy dermatitis.

The veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

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

One treatment provides repellent (anti-feeding) activity against:
- sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks),
- mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks),
- 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 veterinary medicinal product's activity against the vector.

3.3 Contraindications

In the absence of available data the veterinary medicinal 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. Permethrin is dangerous to cats.

3.4 Special warnings

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 veterinary medicinal 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.

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 veterinary medicinal 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 veterinary medicinal 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 to be washed with a shampoo, it should be administered before applying the veterinary medicinal product or at least 2 weeks after application, to optimise efficacy of the veterinary medicinal product.

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 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 animal.

Resistance to permethrin has been reported in fleas, ticks (*Rhipicephalus sanguineus*), in stable flies (*Stomoxys calcitrans*), mosquitoes (*Culex pipiens, Aedes aegypti*) and sand flies (*P. papatasi*). The use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

In the absence of risk of co-infection with fleas, ticks and/or sandflies, a narrow spectrum product should be used.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal product correctly as described under section 3.9. 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product. Seek veterinary advice immediately if this occurs.

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

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

People with known skin sensitivity may be particularly sensitive to this veterinary medicinal 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.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone 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 child-bearing age.

Pregnant women and women suspected of being pregnant should avoid direct contact with the treated animal for 12 hours after the application of the product.
Treated animals should not be handled for at least 12 hours after application of the product. It is therefore recommended to treat the animal in the evening. Treated animals should not be allowed to sleep with their owners, 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.
Avoid contact between the veterinary medicinal 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.
If the veterinary medicinal 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.

This veterinary medicinal product contains butylhydroxytoluene which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Special precautions for the protection of the environment:
Treated dogs should not be allowed to enter surface water for 48 hours after treatment to avoid adverse effects on aquatic organisms.

Other precautions:
The solvent in the 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:

Uncommon (1 to 10 animals / 1,000 animals treated):	Application site itching, application site hair change (e.g. application site greasy fur) Emesis
Rare (1 to 10 animals / 10,000 animals treated):	Application site erythema, application site inflammation, application site hair loss Diarrhoea
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Increased skin sensitivity (scratching, rubbing)[1] Lethargy[1] Behavioural disorder (agitation, restlessness, whining, rolling)[1, 2, 3] Digestive tract disorder (hypersalivation decreased appetite)[1, 2, 3] Neurological signs (e.g. abnormal movement, twitching)[1, 2, 3]

[1] generally self-resolving, [2] transient, [3] in dogs susceptible to permethrin

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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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

The safety of the veterinary medicinal product has not been established in dogs during pregnancy, lactation, or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

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

None known.

3.9 Administration routes and dosage

Spot-on solution for external use only.
Apply only to undamaged skin. Animals should be weighed accurately prior to treatment.

The minimum dose rate is 10 mg/kg bodyweight (bw) imidacloprid and 50 mg/kg bodyweight permethrin, which equates to 1 pipette of 2.5 ml for a dog (>10 kg to 25 kg) corresponding to a dose of 10-25 mg/kg bw imidacloprid and 50-125 mg/kg bw permethrin.

For dogs over 10 kg up to 25 kg:

Remove one pipette from the package. Hold the pipette in an upright position, twist the cap off. Starting from your dog's shoulder, part the fur and squeeze the contents of the pipette in four places along your dog's back, finishing at the base of the tail. Do not apply an excessive amount of solution at any spot that could cause some of the solution to run off the side of the dog.

In case of biting lice 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 the whole period.

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

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

Application of doses equivalent to 5 times the therapeutic dose in healthy adult dogs or puppies has not produced any adverse clinical signs. It is the same in puppies whose mother received 3 times the therapeutic dose of the combination imidacloprid / permethrin. The severity of the skin rash which can sometimes appear at the application site increases with overdose.

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: QP53AC54

4.2 Pharmacodynamics

The veterinary medicinal product is an ectoparasiticide for topical use containing imidacloprid and permethrin. This combination acts as an insecticide, acaricide and as a repellent.

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 veterinary medicinal product provides repellent (anti-feeding) activity against *Phlebotomus perniciosus* (>80% for 3 weeks), mosquitoes and ticks. Field data from an endemic area showed that the veterinary medicinal 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.

Resistance to permethrin may develop and it is known that resistance manifests in single or multiple mutations of its primary target site, the voltage-gated sodium channels (VGSC), commonly referred to as knockdown resistance (kdr- or skdr-mutation). Other mechanisms of resistance development include cuticle thickening and metabolic resistance via over expression of metabolizing P450 mono-oxygenases, esterases, and glutathione-S-transferases.

4.3 Pharmacokinetics

The veterinary medicinal 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.

Environmental properties

The veterinary medicinal 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 3.5.

Imidacloprid and permethrin containing products are toxic to honey bees.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Do not refrigerate or freeze.
Keep the pipettes in the original package in order to protect from light and moisture.

5.4 Nature and composition of immediate packaging

Type of the container:	White polypropylene pipette.
Material of the secondary packaging:	PET/PE/aluminium/surlyn sachet (child resistant) containing one pipette.
Package sizes:	Packs containing 1, 2, 3, 4, 6, 12, and 24 unit dose pipettes. 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 permethrin and 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

Beaphar B.V.

7. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:{DD/MM/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 not subject to prescription: ES, FR, IT, PT.

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Front side: PrevenTix 250 mg/1250 mg spot-on solution for dogs

Back side: PrevenTix 250 mg/1250 mg spot-on solution for dogs up over 10 kg up to 25 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette of 2.5 ml contains:

250 mg imidacloprid
1250 mg permethrin

3. PACKAGE SIZE

1 x 2.5 ml
2 x 2.5 ml
3 x 2.5 ml
4 x 2.5 ml
6 x 2.5 ml
12 x 2.5 ml
24 x 2.5 ml

4. TARGET SPECIES

5. INDICATIONS

[For cartons: this text for front (only) of carton.]
• Kills ticks, fleas and biting lice
• Repels ticks, mosquitos, sand flies, and stable flies
• Reduces the risk of transmission of canine leishmaniosis and canine ehrlichiosis

Pictograms of 6 parasites, i.e. ticks, fleas, biting lice, mosquitoes, sand flies, stable flies

[For cartons: this text for back (only) of carton]
- Treatment and prevention of fleas for 4 weeks; can be used as a part of the strategy of treatment of flea allergic dermatitis (FAD).
- Eliminates biting lice.
- Repels and kills ticks for 3 weeks or 4 weeks depending on the tick species. 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.

- Repels sand flies, mosquitoes and stable flies for between 2 and 4 weeks.
- Reduces the risk of transmission of canine leishmaniosis (for up to 3 weeks) and canine ehrlichiosis (for up to 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.
- Repels sand flies, mosquitoes and stable flies for between 2 and 4 weeks
- Reduces the risk of transmission of canine leishmaniosis (for up to 3 weeks) and canine ehrlichiosis (for up to 4 weeks)

6. ROUTES OF ADMINISTRATION

Spot-on use. External use only.

Use one pipette to treat one dog.

Remains effective if the dog becomes wet. Provides a larvicidal effect against fleas in the immediate surroundings of the treated dogs Do not use on puppies of less than 7 weeks of age or 10 kg of weight. In case of pregnancy or lactation, use only according to the advice of a responsible veterinarian.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Store in the original package, in order to protect from light and moisture.

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

beaphar®

14. MARKETING AUTHORISATION NUMBERS

XXXXXXXX

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Sachet }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PrevenTix

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

250 mg imidacloprid
1250 mg permethrin
2.5 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use the pipette immediately

beaphar®

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PrevenTix

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

250 mg imidacloprid
1250 mg permethrin
2.5 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

beaphar®

B. PACKAGE LEAFLET
To be used for all 4 strengths

PACKAGE LEAFLET

This package leaflet is designed for all 4 strengths/sizes of this product.

1. Name of the veterinary medicinal product

PrevenTix spot-on solution for dogs up to 4 kg.
PrevenTix spot-on solution for dogs over 4 kg up to 10 kg.
PrevenTix spot-on solution for dogs over 10 kg up to 25 kg.
PrevenTix spot-on solution for dogs over 25 kg up to 40 kg.

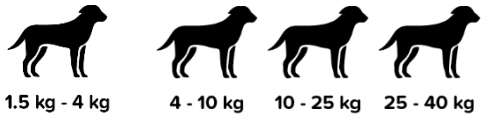
2. Composition

Each white pipette contains:

		Active substance		Excipient(s)	
	Amount (ml)	Imidacloprid (mg)	Permethrin (mg)	Butylhydroxytoluene (mg)	N-methylpyrrolidone (mg)
PrevenTix up to 4 kg	0.4	40.0	200.0	0.4	187
PrevenTix > 4 kg up to 10 kg	1.0	100.0	500.0	1.0	468
PrevenTix > 10 kg up to 25 kg	2.5	250.0	1250.0	2.5	1170
PrevenTix > 25 kg up to 40 kg	4.0	400.0	2000.0	4.0	1872

Clear yellowish spot-on solution.

3. Target species



4. Indications for use

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 veterinary medicinal product can be used as a part of a treatment strategy for flea allergy dermatitis.

The veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

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

One treatment provides repellent (anti-feeding) activity against:
- sand flies (*Phlebotomus papatasi* for two weeks and *Phlebotomus perniciosus* for three weeks),
- mosquitoes (*Aedes aegypti* for two weeks and *Culex pipiens* for four weeks),
- 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 veterinary medicinal product's activity against the vector.

5. Contraindications

Do not use 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. Permethrin is dangerous to cats

6. Special warnings

Special warnings

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 veterinary medicinal 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.

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 veterinary medicinal 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 to be washed with a shampoo, this should be done before applying the veterinary medicinal product or at least 2 weeks after application, to optimise efficacy of the veterinary medicinal product.

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 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 animal.

Resistance to permethrin has been reported in fleas, ticks (*Rhipicephalus sanguineus*), in stable flies (*Stomoxys calcitrans*), mosquitoes (*Culex pipiens, Aedes aegypti*) and sand flies (*P. papatasi*). The use of this product should take into account local information about susceptibility of the target parasites, where available. It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Special precautions for safe use in the target species:

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 veterinary medicinal product. 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product. Seek veterinary advice immediately if this occurs.

As with any antiparasiticide, frequent and repeated use of ectoparasiticide from the same class may lead to the development of resistance.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known skin sensitivity may be particularly sensitive to this veterinary medicinal 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.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone 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 child-bearing age.
Pregnant women and women suspected of being pregnant should avoid direct contact with the treated animal for 12 hours after the application of the product.

Treated animals should not be handled for at least 12 hours after application of the product. It is therefore recommended to treat the animal in the evening. Treated animals should not be allowed to sleep with their owners, 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.
Avoid contact between the veterinary medicinal 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.
If the veterinary medicinal 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.

This veterinary medicinal product contains butylhydroxytoluene which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Other precautions:
As the veterinary medicinal 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 the 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:
The safety of the veterinary medicinal product has not been established in dogs during pregnancy, lactation, lay or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:
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 veterinary medicinal product.

Major incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Application site itching, application site hair change (e.g. application site greasy fur) Emesis
Rare (1 to 10 animals / 10,000 animals treated):	Application site erythema, application site inflammation, application site hair loss Diarrhoea
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Increased skin sensitivity (scratching, rubbing)[1] Lethargy[1] Behavioural disorder (agitation, restlessness, whining, rolling)[1, 2, 3]

	Digestive tract disorder (hypersalivation decreased appetite)[1, 2, 3] Neurological signs (e.g. abnormal movement, twitching)[1, 2, 3]

[1] generally self-resolving, [2] transient, [3] in dogs susceptible to permethrin

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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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.

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

Dosing Scheme & recommended minimum dose for each strength of PrevenTix spot-on:

Dogs size	Product to use	Volume (ml)	Imidacloprid (mg/kg body weight)	Permethrin (mg/kg body weight)
≤ 4 kg	PrevenTix ≤ 4 kg	0.4	minimum of 10	minimum of 50
>4 kg ≤ 10 kg	PrevenTix > 4 kg and ≤ 10 kg	1.0	10 - 25	50 - 125
>10 kg ≤ 25 kg	PrevenTix > 10 kg and ≤ 25 kg	2.5	10 - 25	50 - 125
>25 kg ≤ 40 kg	PrevenTix > 25 and ≤ 40 kg	4.0	10 - 16	50 - 80

Spot-on use.

9. Advice on correct administration

For dogs over 1.5 kg up to 10 kg:
Remove one pipette from the package. Hold the pipette in an upright position, twist the cap off. 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 up to 40 kg:
Remove one pipette from the package. Hold the pipette in an upright position, twist the cap off. Starting from your dog's shoulder, part the fur and squeeze the contents of the pipette in four places along your dog's back, finishing at the base of the tail. Do not apply an excessive amount of solution at any spot that could cause some of the solution to run off the side of the dog.

For all dogs:
Apply to undamaged skin. Animals should be weighed accurately prior to treatment.

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.

In case of biting lice 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 sandfly season, treatment should be compliantly continued throughout the whole period.

10. Withdrawal periods

11. Special storage precautions

Keep out of the sight and reach of children.

Do not refrigerate or freeze.
Store in the original container in order to protect from light and moisture.

Do not use this veterinary medicinal product after the expiry date which is stated on the packaging.

12. Special precautions for disposal

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

The veterinary medicinal product should not enter water courses as permethrin and 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 not subject to prescription: ES, FR, IT, PT.

14. Marketing authorisation numbers and pack sizes

Packs containing 1, 2, 3, 4, 6, 12, and 24 unit dose pipettes, packed individually in a child resistant sachet. 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*.

16. Contact details

Marketing authorisation holder
Beaphar B.V.
Drostenkamp 3
8101 BX Raalte
The Netherlands

Manufacturer responsible for batch release:
Beaphar B.V.
Oude Linderteseweg 9
8102 EV Raalte
The Netherlands

Local representatives and contact details to report suspected adverse reactions.

To be completed in the national phase.

17. Other information

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