ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BROADLINE spot-on solution for cats < 2.5 kg
BROADLINE spot-on solution for cats 2.5-7.5 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Each unit dose applicator delivers:

	Volume of unit dose (ml)	Fipronil (mg)	(S)-methoprene (mg)	Eprinomectin (mg)	Praziquantel (mg)
Cats <2.5 kg	0.3	24.9	30.0	1.20	24.9
Cats 2.5–7.5 kg	0.9	74.7	90.0	3.60	74.7

Excipients:

Butylhydroxytoluene (E321) 1 mg/ml.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear colourless to yellow to red/brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

For cats with, or at risk from mixed infestations by cestodes, nematodes and ectoparasites. The veterinary medicinal product is exclusively indicated when all three groups are targeted at the same time.

Ectoparasites
- Treatment and prevention of infestations by fleas (*Ctenocephalides felis)*. Elimination of fleas within 24 hours. One treatment prevents further infestations for at least one month.
- Prevention of environmental flea contamination by inhibiting the development of flea immature stages (eggs, larvae and pupae) for over a month.
- The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).
- Treatment and prevention of infestations by ticks (*Ixodes ricinus)*. Elimination of ticks within 48 hours. One treatment prevents further infestations for up to 3 weeks.
- Treatment of notoedric mange (*Notoedres cati*).

Cestodes
- Treatment of infestations with tapeworms (*Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis , Joyeuxiella pasqualei* (adult), and *Joyeuxiella fuhrmanni (*adult*)).*

Nematodes
- Treatment of infestations with gastrointestinal nematodes (L3, L4 larvae and adults of *Toxocara cati*, adults of *Toxascaris leonina*, L4 larvae and adults of *Ancylostoma tubaeforme* and *Ancylostoma ceylanicum*, and adults of *Ancylostoma brazilienze*).
- Treatment of infestations with feline lungworms (L3 larvae, L4 larvae and adults of *Aelurostrongylus abstrusus* , L4 larvae and adults of *Troglostrongylus brevior)*.
- Treatment of infestations with vesical worms (*Capillaria plica*).
- Prevention of heartworm disease (*Dirofilaria immitis* larvae) for one month.

4.3 Contraindications

Do not use in sick or convalescent animals.
Do not use in rabbits.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

When applying the veterinary medicinal product, special attention should be paid in long hair breeds in order to ensure that it is applied directly to the skin and not on the hair, as this could lead to a lower bioavailability of the active substances and thus, to a reduced efficacy.

No data on the effect of bathing/shampooing on the efficacy of the veterinary medicinal product in cats is available. However, brief contact of the animal with water on one or two occasions within the month following application is unlikely to significantly reduce its efficacy. As a precaution, it is not recommended to bathe animals within 2 days after topical treatment.

After treatment with BROADLINE, ticks will generally be killed within 48 hours after infestation without having a blood meal. However, since the attachment of single ticks after treatment cannot be excluded transmission of infectious diseases cannot be completely ruled out.

Tapeworm infestation may reoccur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

In certain individual cats *Notoedres cati* infestation may be severe or complicated by bacterial infections. In these severe cases concomitant treatment may be necessary.

Parasite resistance to any particular class of antiparasitic drug may develop following frequent use of a compound of that class. Therefore, epidemiological information about current susceptibility of the target species should be taken into account in order to limit the possibility of a future selection for resistance.

Cats in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Although the veterinary medicinal product may be safely administered to cats infected with adult heartworms, no therapeutic effect against adult *Dirofilaria immitis* has been established. It is therefore recommended that all cats 6 months of age or more, living in areas endemic for heartworm, should be tested for existing adult heartworm infestation before being treated with the product for heartworm prevention.

Some cats with patent *Joyeuxiella spp*. infestation may nevertheless harbour a high proportion of juvenile worms, which are not susceptible to the product; therefore a post-treatment follow-up is recommended in case of such infestations.

To reduce re-infestation from emergence of new fleas, it is recommended that all cats in a household be treated. Other animals living in the same household should also be treated with a suitable product.

All stages of fleas can infest the cat's basket, bedding and regular resting areas such as carpets and soft furnishings. In case of massive flea infestation and at the beginning of the control measures, these areas should be treated with a suitable environmental product and then vacuumed regularly.

4.5 Special precautions for use

Special precautions for use in animals

Spot-on application only. Do not inject, do not administer orally or via any other route. Avoid contact with the cat's eyes.

It is important to apply the veterinary medicinal product to a skin area where the cat cannot lick it off: on the neck, in between shoulders. Avoid animals licking each other following treatment.

Oral ingestion of the veterinary medicinal product resulted in common to uncommon vomiting, hypersalivation and/or in transient neurological signs such as ataxia, disorientation, apathy and pupil dilation in safety studies. Muscle tremors have been reported in very rare cases based on post marketing safety experience. These signs usually resolve spontaneously within 24 hours. On very rare occasions, symptomatic treatment can be required.

The safety of the veterinary medicinal product has not been tested at intervals of less than 2 weeks or in kittens weighing less than 0.6 kg and/or under 7 weeks of age. The product is not for use in kittens weighing less than 0.6 kg and/or under 7 weeks of age.

The veterinary medicinal product is not intended for use in dogs. Some dog breeds may present increased susceptibility to macrocyclic lactones, potentially leading to signs of neurotoxicity. Oral uptake by dogs, specifically by Collies, Old English Sheepdogs and related breeds or crossbreeds should thus be avoided.

Echinococcosis represents a hazard for humans, and is a notifiable disease to the World Organisation for Animal Health (OIE).

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

Do not smoke, drink or eat during application.
Wear gloves when handling the veterinary medicinal product. Wash hands immediately after use.
Unused applicators must be stored in the intact blister package.

Avoid contact of the applicator content with the fingers. If this occurs, wash off with soap and water. In case of accidental eye exposure, flush the eyes thoroughly with water as the product can cause slight mucous membrane and eye irritation. If eye irritation persists or if side effects are noted, seek medical advice and show the package leaflet or the label to the physician.

Handling of treated animals should be limited until the application site is dry. Children should not be allowed to play with treated animals during this period. Recently treated animals should not sleep with owners, especially children.

People with a known hypersensitivity to fipronil, (S)-methoprene, eprinomectin or praziquantel or to any of the excipients should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

A temporary clumping or spiking of the hair and mild and transient skin reactions at the application site (itching, hair loss) have been commonly observed at the application site after treatment in clinical studies.

Temporary excessive salivation was commonly observed following licking the application site after treatment in clinical trials.
Digestive tract and/or neurological disorders may result following an accidental oral ingestion of the veterinary medicinal product (see section 4.5). Transitory blindness or impaired vision have been observed in very rare cases based on post marketing safety experience.

Symptomatic treatment can be required if the signs do not resolve spontaneously within 24 hours. Correct application will minimise the occurrence of such events (see section 4.9).

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies with the individual ingredients in rats and rabbits have not produced teratogenic, foetotoxic or maternotoxic effects. Use only according to the benefit-risk assessment by the prescribing veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Spot-on use.

The use of the veterinary medicinal product should exclusively be based on the confirmed mixed infestations or significant risk of such mixed infestation with ectoparasites and nematodes (including for heartworm disease prevention) and where concurrent treatment against cestodes is indicated. In the absence of risk of co-infestation, the use of a narrow spectrum parasiticide should be considered as a first line therapy.

The rationale for prescription should be tailored to the individual needs of the cat, based on clinical assessment, the animal's lifestyle and on the local epidemiological situation (including zoonotic risks, where relevant) in order to address exclusively situations of mixed infestations/risk of infestation.

Treatment should not be extrapolated from one animal to the other without veterinary opinion.

Dosage:

The recommended minimum doses are 10 mg/kg bodyweight for fipronil, 12 mg/kg for (S)-methoprene, 0.5 mg/kg for eprinomectin and 10 mg/kg for praziquantel.

Select the appropriate applicator size for the weight of the cat.

Cat weight	Volume of unit dose (ml)	Fipronil (mg)	S-methoprene (mg)	Eprinomectin (mg)	Praziquantel (mg)
< 2.5 kg	0.3	25	30	1.2	25
2.5-7.5 kg	0.9	75	90	3.6	75
> 7.5 kg	appropriate combination of applicators				

Method of administration:

Use a pair of scissors to cut the blister along the dotted line, then pull the lid away.
Remove the applicator from the package and hold it upright. Pull back the plunger slightly, twist and pull off the cap. Part the hair on the midline of the neck, between the base of the skull and the shoulder blades until the skin is visible. Place the tip of the applicator on the skin and apply the entire content directly onto the skin in one spot.

Prevention of heartworm disease (*Dirofilaria immitis* larvae) should start within 1 month after the first expected exposure to mosquitoes.
For treatment against *Aelurostrongylus abstrusus*, a second administration one month after the initial treatment may be recommended.

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

Safety has been demonstrated with up to 5 times the maximum exposure dose (i.e. up to 15 times the recommended dose) in healthy kittens aged 7 weeks and older treated up to 6 times at four-week intervals. It has also been confirmed in healthy adult cats treated 3 times at two-week intervals with up to 5 times the recommended doses. Mild and transient neurological signs such as ataxia, disorientation, apathy and pupil dilation may be observed, with spontaneous recovery the day after. Transient salivation and/or vomiting could also be observed, both in kittens and adult cats, in isolated cases.

Cats infected with adult heartworms tolerated up to 3 times the maximum exposure dose (i.e. up to 9 times the recommended dose), every 4 weeks for 3 treatments, without any adverse effects.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic products, insecticides, avermectins, eprinomectin in combinations.
ATC vet code: QP54AA54.

The veterinary medicinal product is a spot-on solution for topical use containing the insecticidal and acaricidal active ingredients fipronil (adulticide) and (S)-methoprene (ovicidal and larvicidal), combined with the endectocide eprinomectin and the cestocide praziquantel to complete the broad spectrum with activity against gastrointestinal nematodes, lungworms and tapeworms, and vesical worms.

5.1 Pharmacodynamic properties

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. Fipronil and its metabolite fipronil sulfone act at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA) as well as desensitising (D) and non-desensitising (N) channels gated by glutamate (Glu, unique invertebrate ligand-gated chloride

channels), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarians.

(S)-Methoprene is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues that inhibit the development of immature stages of insects. This compound mimics the action of juvenile hormone and causes impaired development and death of the developing stages of fleas. The on-animal ovicidal activity of (S)-methoprene results from either direct penetration of the eggshell of newly laid eggs or from absorption through the cuticle of the adult fleas. (S)-Methoprene is also effective in preventing flea larvae and pupae from developing, which prevents contamination of the environment of the treated animals with the immature stages of fleas.

Eprinomectin is a member of the macrocyclic lactone class of endectocides. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve or muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarisation of the nerve or muscle cell, resulting in paralysis and death of the parasite. The spectrum of efficacy of eprinomectin has been shown to cover gastrointestinal and extraintestinal nematodes.

Praziquantel is a synthetic isoquinoline-pyrazine derivative with activity against tapeworms. Praziquantel is rapidly adsorbed via the surface of the parasites and affects membrane permeability in cestodes, influencing divalent cation fluxes, particularly calcium ion homeostasis, which is thought to contribute to the rapid muscle contraction and vacuolisation. This results in severe damage to the parasite integument, contraction and paralysis, disruption of metabolism and finally leads to the death and expulsion of the parasite. Disintegrated and partially digested fragments may occasionally be seen in the faeces.

5.2 Pharmacokinetic particulars

The ectoparasitic activity of fipronil and (S)-methoprene is mediated by direct contact with the ectoparasites rather than by systemic exposure. After a single topical application of the veterinary medicinal product, the actives were detected at various regions of the cat's body, including the caudal region, within the first days of application, indicating distribution/movement from the site of application (between the head and shoulder blades) across the body of the animal.
Fipronil sulfone, as a photodegradation product of fipronil, is also found on the hair. The concentrations in the hair coat of fipronil, fipronil sulfone and (S)-methoprene decrease with time but remain detectable for at least 42 days after dosing. The topical application, with additional potential oral exposure from grooming, also results in partial systemic exposure that decreases over time.
The peak plasma concentrations of the absorbed fraction of fipronil and (S)-methoprene are reached within 8 to 9 hours. Unlike other species, fipronil sulfone is not formed in cat. Fipronil is mainly excreted in the faeces as unchanged drug. (S)-methoprene, once absorbed, is very quickly metabolised and excreted.

Eprinomectin and praziquantel act systemically, with plasma concentrations reaching a maximum within 48 hours and 6 hours after treatment, respectively, reaching mean maximum concentrations (C_{max}) of 20.1 ng/ml for eprinomectin and 157 ng/ml for praziquantel.
Once absorbed, eprinomectin is highly bound to plasma proteins (> 99%), has low clearance from blood, and distributes well into tissues. Its metabolism is limited, and it is mainly excreted unchanged in the faeces. The average half-life for this compound is 4.75 days. Praziquantel has a moderate tissue distribution, and about 64–84% of praziquantel is bound to plasma proteins. Praziquantel undergoes hepatic metabolism followed by renal excretion. The average half-life for praziquantel is 3.08 days.

In vitro metabolism assays and in vivo studies have demonstrated that there are no pharmacodynamic or pharmacokinetic interactions between fipronil, (S)-methoprene, eprinomectin and praziquantel.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal
Disodium edetate (E385)
Propyl gallate (E310)
Thiodipropionic acid
Dimethyl isosorbide
Butylhydroxytoluene (E321)

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Store the applicator in the blister package in order to protect from light.
Keep the unused applicator in the intact blister package.
Opened applicators should be disposed of immediately.

6.5 Nature and composition of immediate packaging

Unit dose syringe-shaped applicators (clear siliconised cyclic olefin copolymer (COC)) containing 0.3 ml or 0.9 ml of product, closed with a polymer cap and placed in individual plastic blisters.

Cardboard box containing 1, 3, 4 or 15 applicator(s) (0.3 ml each).
Cardboard box containing 1, 3, 4, 6 or 15 applicator(s) (0.9 ml each).

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

Any unused veterinary medicinal product or waste material derived from it should be disposed of in accordance with local requirements.
BROADLINE or empty container should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/157/001–009

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04/12/2013
Date of latest renewal: 24/09/2018

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet,
31000 Toulouse
FRANCE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box, pack sizes of 1, 3, 4, 6 or 15 applicators

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BROADLINE spot-on solution for cats < 2.5 kg
BROADLINE spot-on solution for cats 2.5–7.5 kg

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose:

Fipronil	24.9 mg
(S)-Methoprene	30.0 mg
Eprinomectin	1.20 mg
Praziquantel	24.9 mg

Fipronil	74.7 mg
(S)-Methoprene	90.0 mg
Eprinomectin	3.60 mg
Praziquantel	74.7 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

0.3 ml
3 x 0.3 ml
4 x 0.3 ml
15 x 0.3 ml

0.9 ml
3 x 0.9 ml
4 x 0.9 ml
6 x 0.9 ml
15 x 0.9 ml

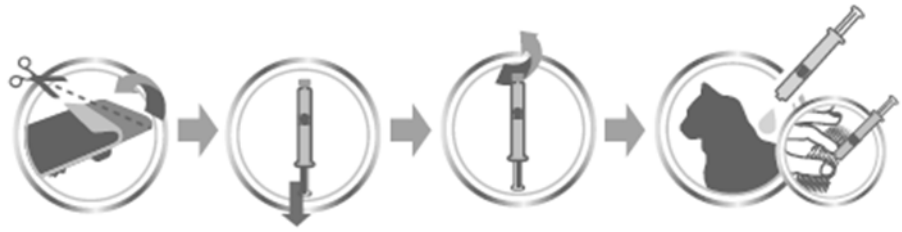
5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.
External use only.
Read the package leaflet before use.



8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Keep the unused applicator in the intact blister.

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. To be supplied only on veterinary prescription.

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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/157/001	0.3 ml
EU/2/13/157/002	3 x 0.3 ml
EU/2/13/157/003	4 x 0.3 ml
EU/2/13/157/008	15 x 0.3 ml
EU/2/13/157/004	0.9 ml
EU/2/13/157/005	3 x 0.9 ml
EU/2/13/157/006	4 x 0.9 ml
EU/2/13/157/007	6 x 0.9 ml
EU/2/13/157/009	15 x 0.9 ml

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNIT

Applicator

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BROADLINE

2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.3 ml
0.9 ml

3. ROUTE OF ADMINISTRATION

4. WITHDRAWAL PERIOD(S)

Not applicable.

5. BATCH NUMBER

Lot

6. EXPIRY DATE

EXP

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BROADLINE spot-on solution for cats <2.5 kg
BROADLINE spot-on solution for cats 2.5–7.5 kg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
BROADLINE spot-on solution for cats < 2.5 kg
BROADLINE spot-on solution for cats 2.5–7.5 kg

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

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet,
31000 Toulouse
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BROADLINE spot-on solution for cats < 2.5 kg
BROADLINE spot-on solution for cats 2.5–7.5 kg

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

Each unit dose (applicator) delivers:

	Volume of unit dose (ml)	Fipronil (mg)	(S)-methoprene (mg)	Eprinomectin (mg)	Praziquantel (mg)
Cats <2.5 kg	0.3	24.9	30.0	1.20	24.9
Cats 2.5-7.5 kg	0.9	74.7	90.0	3.60	74.7

Excipient: Butylhydroxytoluene (E321) 1 mg/ml.
Spot-on solution.

4. INDICATIONS

For cats with, or at risk from mixed infestations by cestodes, nematodes and ectoparasites. The veterinary medicinal product is exclusively indicated when all three groups are targeted at the same time.

Ectoparasites
- Treatment and prevention of infestations by fleas (*Ctenocephalides felis)*. Elimination of fleas within 24 hours. One treatment prevents further infestations for at least one month.
- Prevention of environmental flea contamination by inhibiting the development of flea immature stages (eggs, larvae and pupae) for over a month.
- The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).
- Treatment and prevention of infestations by ticks (*Ixodes ricinus)*. Elimination of ticks within 48 hours. One treatment prevents further infestations for up to 3 weeks.
- Treatment of notoedric mange (*Notoedres cati*).

Cestodes
- Treatment of infestations with tapeworms (*Dipylidium caninum*, *Taenia taeniaeformis*, *Echinococcus multilocularis*, *Joyeuxiella pasqualei* (adult), *Joyeuxiella fuhrmanni* (adult)).

Nematodes
- Treatment of infestations with gastrointestinal nematodes (L3, L4 larvae and adults of *Toxocara cati*, adults of *Toxascaris leonina* , L4 larvae and adults of *Ancylostoma tubaeforme* and *Ancylostoma ceylanicum*, and adults of *Ancylostoma brazilienze*).
- Treatment of infestations with feline lungworms (L3 larvae, L4 larvae and adults of *Aelurostrongylus abstrusus*, L4 larvae and adults of *Troglostrongylus brevior*).
- Treatment of infestations with vesical worms (*Capillaria plica*).
- Prevention of heartworm disease (*Dirofilaria immitis* larvae) for one month.

5. CONTRAINDICATIONS

Do not use in sick (e.g. systemic diseases, fever) or convalescent animals.
Do not use in rabbits.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

A temporary clumping or spiking of the hair and mild, transient skin reactions at the application site (itching, hair loss) have been commonly observed at the application site after treatment in clinical studies.

Temporary excessive salivation was commonly observed following licking the application site after treatment in clinical trials.

Digestive tract and/or neurological disorders may result following an accidental oral ingestion of the veterinary medicinal product (see section 'Special precautions for use in animals' under SPECIAL WARNINGS). Transitory blindness or impaired vision have been observed in very rare cases based on post marketing safety experience.

Symptomatic treatment can be required if the signs do not resolve spontaneously within 24 hours. Correct application will minimise the occurrence of such events (see section DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION).

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

Cats

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

For topical application onto the skin (spot-on).

The recommended minimum doses are 10 mg/kg bodyweight for fipronil, 12 mg/kg for (S)-methoprene, 0.5 mg/kg for eprinomectin and 10 mg/kg for praziquantel. Select the applicator size (or combination of applicators, for cats >7.5 kg) adapted to the cat's weight.

The use of the veterinary medicinal product should exclusively be based on the confirmed mixed infestations or significant risk of such mixed infestation with ectoparasites and nematodes (including for heartworm disease prevention) and where concurrent treatment against cestodes is indicated. In the absence of risk of co-infestation, the use of a narrow spectrum parasiticide should be considered as a first line therapy.

The rationale for prescription should be tailored to the individual needs of the cat, based on clinical assessment, the animal's lifestyle and on the local epidemiological situation (including zoonotic risks, where relevant) in order to address exclusively situations of mixed infestations/risk of infestation.

Treatment should not be extrapolated from one animal to the other without veterinary opinion.

Prevention of heartworm disease (*Dirofilaria immitis* larvae) should start within 1 month after the first expected exposure to mosquitoes.
For treatment against *Aelurostrongylus abstrusus*, a second administration one month after the initial treatment may be recommended.

9. ADVICE ON CORRECT ADMINISTRATION

Use the applicator size adapted to the weight of the cat.
- Use a pair of scissors to cut the blister along the dotted line, then pull the lid away.
- Remove the applicator from the package and hold it upright.
- Pull back the plunger slightly, twist and pull off the cap.
- Part the hair on the midline of the neck, between the base of the skull and the shoulder blades until the skin is visible.
- Place the tip of the applicator on the skin and apply the entire content directly onto the skin in one spot.
- The product should be applied to dry skin in an area where the cat cannot lick it off. In long hair breeds, special attention should be paid to apply the product onto the skin, and not on the hair to ensure optimal efficacy.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store the applicator in the blister package in order to protect from light.
Keep the unused applicator in the intact blister package.
Opened applicators should be disposed of immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP.

12. SPECIAL WARNINGS

Special warnings for each target species:
Avoid animals licking each other following treatment.

After treatment, ticks will generally be killed within 48 hours after infestation without having a blood meal. However there may be attachment of single ticks and transmission of infectious diseases cannot thus be completely excluded if conditions are unfavourable.

The effect of shampooing or immersion in water of the animal has not been tested and should be avoided. Brief contact of the animal with water within the month following application is unlikely to reduce the efficacy of the product. However, as a precaution, it is not recommended to bath animals within 2 days after treatment.

Tapeworm infestation may reoccur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

Parasite resistance to any particular class of antiparasitic drug may develop following frequent use of a compound of that class. Therefore, epidemiological information about current susceptibility of the target species should be taken into account in order to limit the possibility of a future selection for resistance.

In certain individual cats, *Notoedres cati* infestation may be severe or complicated by bacterial infections. In these severe cases concomitant treatment may be necessary.

Cats in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Although the product may be safely administered to cats infected with adult heartworms, no therapeutic effect against adult *Dirofilaria immitis* has been established. It is therefore recommended that all cats 6 months of age or more, living in areas endemic for heartworm, should be tested for existing adult heartworm infestation before being treated with the product for heartworm prevention.

Some cats with patent *Joyeuxiella spp*. infestation may nevertheless harbour a high proportion of juvenile worms, which are not susceptible to the product; therefore a post-treatment follow-up is recommended in case of such infestations.

To reduce re-infestation from emergence of new fleas, it is recommended that all cats in a household be treated. Other animals living in the same household should also be treated with a suitable product.

All stages of fleas can infest the cat’s basket, bedding and regular resting areas such as carpets and soft furnishings. In case of massive flea infestation and at the beginning of the control measures, these areas should be treated with a suitable environmental product and then vacuumed regularly.

Special precautions for use in animals:
Spot-on application only. Do not inject, do not administer orally or via any other route. Avoid contact with the cat's eyes.

It is important to apply the veterinary medicinal product to a skin area where the cat cannot lick it off: on the neck, in between shoulders. Avoid animals licking each other following treatment.

Oral ingestion of the veterinary medicinal product resulted in common to uncommon vomiting, hyper-salivation and/or in transient neurological signs such as ataxia, disorientation, apathy and pupil dilation in safety studies. Muscle tremors have been reported in very rare cases based on post marketing safety experience. These signs usually resolve spontaneously within 24 hours. On very rare occasions, symptomatic treatment can be required.

The safety of the veterinary medicinal product has not been tested at intervals of less than 2 weeks or

in kittens weighing less than 0.6 kg and/or under 7 weeks of age. The product is not for use in kittens weighing less than 0.6 kg and/or under 7 weeks of age.

The veterinary medicinal product is not intended for use in dogs. Some dog breeds may present increased susceptibility to macrocyclic lactones, potentially leading to signs of neurotoxicity. Oral uptake by dogs, specifically by Collies, Old English Sheepdogs and related breeds or crossbreeds should thus be avoided.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke, drink or eat during application.
Wear gloves when handling the veterinary medicinal product. Wash hands immediately after use.

Avoid contact of the applicator content with the fingers. If this occurs, wash off with soap and water. In case of accidental eye exposure, flush the eyes thoroughly with water as the product can cause slight mucous membrane and eye irritation. If eye irritation persists or if side effects are noted, seek medical advice and show the package leaflet or the label to the physician.

Handling of treated animals should be limited until the application site is dry. Children should not be allowed to play with treated animals during this period. Recently treated animals should not sleep with owners, especially children.

People with a known hypersensitivity to fipronil, (S)-methoprene, eprinomectin or praziquantel or to any of the excipients should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies with the individual ingredients in rats and rabbits have not produced teratogenic, foetotoxic or maternotoxic effects. Use only according to the benefit-risk assessment by the prescribing veterinarian.

Overdose (symptoms):
Safety has been demonstrated with up to 5 times the maximum exposure dose (i.e. up to 15 times the recommended dose) in healthy kittens aged 7 weeks and older treated up to 6 times at four-week intervals. It has also been confirmed in healthy adult cats treated 3 times at two-week intervals with up to 5 times the recommended doses. Mild and transient signs may be observed with spontaneous recovery the day after – see description in section ADVERSE REACTIONS.
Cats infected with adult heartworms tolerated up to 3 times the maximum exposure dose (i.e. up to 9 times the recommended dose), every 4 weeks for 3 treatments, without any adverse effects.

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

BROADLINE or empty container should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Ask your veterinary surgeon 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

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Echinococcosis represents a hazard for humans, and is a notifiable disease to the World Organisation for Animal Health (OIE).

Cardboard box containing 1, 3, 4 or 15 unit dose applicator(s) of 0.3 ml each.
Cardboard box containing 1, 3, 4, 6 or 15 unit dose applicator(s) of 0.9 ml each.

Not all pack sizes may be marketed.