

**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

**STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**  
 Each unit dose (applicator) delivers:

BROADLINE spot-on solution	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

**PRODUCT DESCRIPTION**  
 Clear colourless to yellow to red/brown solution.

**PHARMACODYNAMICS**  
 Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. Fipronil and its metabolite fipronil sulfonate 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 hyperpolarization 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 absorbed via the surface of the parasite 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 vasodilation. 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.

**PHARMACOKINETICS**  
 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 day 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 concentration 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 result in partial systemic exposure that decreases over time. The peak plasma concentrations of the absorbed fraction of fipronil and S-methoprene are reached in 8 to 9 hours. Unlike other species, fipronil sulfonate is not formed in cat. Fipronil is mainly excreted in the faeces as unchanged drug. S-methoprene, once absorbed, is very quickly metabolized 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<sub>max</sub>) of 20.1ng/ml for eprinomectin and 157ng/ml for praziquantel. Once absorbed, eprinomectin is

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				

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.

**ADVICE ON CORRECT 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.

**WITHDRAWAL PERIOD**  
 Not applicable.

**SPECIAL STORAGE PRECAUTIONS**  
 Store below 30°C. Keep out of the sight and reach of children. Store in the original cardboard package in order to protect from light.

**SPECIAL WARNINGS**  
 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 disease cannot be completely ruled out.  
 Tapeworm infestation may recur 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 be 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 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 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 Collies, Old English Sheepdogs and related breeds or crossbreeds should thus be avoided. Echinococcosis represents a hazard for humans, and is 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. Wash hands immediately after use or wear suitable gloves when applying the product to cat. 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, and children should not be allowed to play with treated animals during this period. It is therefore recommended that recently treated animals do not sleep with owners, especially children. People with a known hypersensitivity to any of the active ingredients or 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 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

**GRAPHIC ARTWORK APPROVAL**

LABEL CODE: 5LBROAS3-003	VERSION	COLORS
PRODUCT: Broadline spot on solution for cats PACK SIZE: COUNTRY: MY DIMENSIONS: cm = 42 x 29.17	VERSION: 6 MM/YY:	<b>P 335</b>

Marketing approval:	Regulatory approval:	GMP approval:
COMPLETE NAME: DATE: SIGNATURE:	COMPLETE NAME: DATE: SIGNATURE:	COMPLETE NAME: DATE: SIGNATURE:

