SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Fipronil 50 mg spot-on solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 0.50 ml pipette contains:

Active substance:

Fipronil	50 mg

Excipients:

Butylhydroxyanisole E320	0.100 mg
Butylhydroxytoluene E321	0.050 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear, pale amber solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

Treatment of flea (*Ctenocephalides spp*.) infestations.

Fleas will be killed within 24 h. The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides spp*.).

Although no immediate killing effect against ticks has been demonstrated, the product has shown an acaricidal efficacy against *Dermacentor reticulatus*. If ticks of this species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they will be killed within a week.

The 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.

4.3 Contraindications

Do not use on kittens less than 2 months old and/or weighing less than 1 kg.
Do not use on sick (systemic diseases, fever…) or convalescent animals.
Do not use in rabbits, as adverse drug reactions and even death could occur.
Do not use on animals with known hypersensitivity to the active substance or to any of excipients.

4.4 Special warnings for each target species

Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

Avoid frequent swimming or shampooing the animal because the maintenance of effectiveness of the product in these cases has not been tested.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs and cats in the household are recommended.

4.5 Special precautions for use

Special precautions for use in animals

Avoid contact with the animal’s eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

Do not apply the product on wounds or damaged skin.

It is important to make sure that the product is applied to an area where the animal cannot lick it off, and to make sure that animals do not lick each other following treatment.

Specific studies in cats investigating the safety of the product following repeated administration or at over-dosage have not been conducted due to the known safety profile of the active substances and excipients.

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

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.
In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician.
Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.

Do not smoke, drink or eat during application.
Animals or people with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the product. Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals should not be allowed to sleep with owners, especially children.
Keep pipettes in the original packaging and dispose of used pipettes immediately.

Other precautions

The product may have adverse effects on painted, varnished or other household surfaces or furnishings.

4.6 Adverse reactions (frequency and seriousness)

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (squamosis, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms) or vomiting have been observed after use.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effects. Studies have not been carried out with this product in pregnant and lactating queens. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

<u>Route of administration and dosage:</u>
External use only.

Administer by topical application to the skin 1 pipette of 0.5 ml per animal.

Remove the pipette from the blister packaging. Hold the pipette in an upright position and snap off the top section of the cap, thereby opening the pipette.

Part the pet's coat until the skin is visible. Place the tip of the tube directly against the bared skin and squeeze gently. Empty approximately half the contents at each of two points along the cat's back. The first application point is at the base of the head and the second application point is between the shoulder blades. Squeeze the tube several times to ensure dosing is complete. Avoid applying the solution onto the fur and do not rub into the skin.

Application of the solution as directed minimises the possibility that the animal will lick the solution off.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will usually disappear within 24-48 hours post application. Crystals may be seen on the hair and slight scaling may occur within 24-48 hours after application.

Treatment schedule:

For optimal control of flea infestation the treatment schedule can be based on the local epidemiological situation.

The minimum interval between two treatments is 4 weeks.

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

The toxicity of the veterinary medicinal product when administered to the skin is very low. The risk of experiencing adverse effects (see section 4.6) may increase in cases of over-dose, so animals should always be treated with the correct product according to species and bodyweight.
No adverse effects were observed in a target animal safety study in eight weeks-old cats weighing about 1 kg treated with 5 times the therapeutic dose monthly for three months.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use.
ATCvet code: QP53AX15

5.1 Pharmacodynamic properties

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by inhibiting the GABA complex, binding to the chloride channel and 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 acarids. Fipronil exhibits an insecticidal and acaricidal activity against fleas (*Ctenocephalides spp*.) and acaricidal activity against ticks (*Dermacentor reticulatus*) in the cat.

5.2 Pharmacokinetic particulars

In vitro, fipronil is mainly metabolised with subcellular liver fractions to its sulfone derivative. However, this may be of limited relevance ‘in vivo’ as fipronil is poorly absorbed in the cat. The concentrations of fipronil on the hair decrease with time.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole E320
Butylhydroxytoluene E321
Benzyl alcohol E1519
Diethylene glycol monoethyl ether

6.2 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 below 25°C, in a dry place in the original packaging.

6.5 Nature and composition of immediate packaging

White opaque or pink or green translucent polypropylene single-dose pipettes containing an extractable volume of 0.5 ml packaged in a clear PVC blister closed by heat sealing with aluminium foil and placed in a carton box or blister card.
Blister cards or boxes of 1, 2, 3, 4, 5 or 6 pipettes.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

7. MARKETING AUTHORISATION HOLDER

Pets Choice Limited
Brentwood House
Lower Philips Road
Whitebirk Industrial Estate
Blackburn
Lancashire
BB1 5UD
United Kingdom

8. MARKETING AUTHORISATION NUMBER

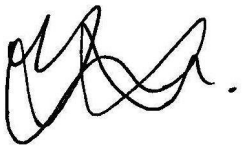
Vm 52797/4009

9. DATE OF FIRST AUTHORISATION

14 December 2011

10. DATE OF REVISION OF THE TEXT

May 2020



Approved: 29 May 2020