SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Spot On Solution 50 mg for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 0.5 mL pipette contains:

Active substance:

Fipronil	50.00 mg

Excipients:

Butylhydroxyanisole (E320)	0.10 mg
Butylhydroxytoluene (E321)	0.05 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 felis*) infestations. The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides felis*).

The product has shown acaricidal efficacy against *Dermacentor reticulatus* infestations one week after application; however, no acaricidal efficacy was seen immediately after treatment or two weeks after treatment. 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.

4.3 Contraindications

Do not use on kittens less than 2 months old and/or weighing less than 1 kg.
Do not use on animals that are unwell, are undergoing treatment for, or are recovering from illness.

Do not use in rabbits! 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

During the period of expected efficacy (i.e. one week after treatment), ticks will be killed and fall off the host within 48 hours after infestation without having had a blood meal as a rule but an attachment of single ticks after treatment cannot be excluded. A transmission of infectious diseases by ticks cannot thus be excluded. Once dead, ticks will often drop off the animal, but any remaining ticks may easily be removed by a gentle pull.

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.

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.

The safety of the product has not been investigated in studies where overdose or repeated dosing were used due to the well-known safety profile of the active substance and the other ingredients.

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.

People with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the veterinary medicinal 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.

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 excessive salivation / drooling may be observed due mainly to the solvents in the product.

Among the extremely rare suspected adverse reactions, short duration skin reactions at the application site (scaly skin, hair loss at the application site, skin irritation, itching and reddening) and general skin irritation or hair loss have been reported after use. Rarely, excessive drooling / salivation, and reversible nervous signs (e.g. excitability, depression) or vomiting have been observed after use.

4.7 Use during pregnancy, lactation or lay

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effect. The safety of the product was not demonstrated in breeding, pregnant and lactating queens. The product can be use only during pregnancy and lactation according to the benefit/risk assessment performed by the responsible 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
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 pipette directly against the bared skin and squeeze gently. Empty approximately half the contents at two points along the cat's back, preferably at the base of the head and between the shoulder blades. Squeeze

the pipette 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. There is little evidence available from studies with this product in cats; however, from studies in dogs, crystals may be seen on the hair and slight scaling may occur within 24-48 hours after application.

Treatment schedule:

The minimum interval between two treatments is 4 weeks. In some cases longer intervals between treatments may be appropriate. For advice speak to your veterinary surgeon.

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

The risk of adverse effects (see section 4.6) with the veterinary medicinal product when administered to the skin is very low. The risk may increase in cases of over-dose, so animals should always be treated with the correct product according to species and bodyweight. Be certain to select and use the correct product for your pet.

4.11 Withdrawal period(s)

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 activity against fleas (*Ctenocephalides felis*) and acaricidal activity against ticks (*Dermacentor reticulatus*) in the cat.
Fleas will be killed within 24 h. Ticks will usually be killed within two weeks after contact with fipronil.

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)
Propylene glycol
Benzyl alcohol
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. Store in the original packaging. Store in a dry place.

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 Healthcare Limited
38 Main Street
Swords
Dublin
K67E 0A2
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 61560/3005

9. DATE OF FIRST AUTHORISATION

27 May 2011

10. DATE OF REVISION OF THE TEXT

October 2025

Gavin Hall
Approved: 27 October 2025