

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Silent Flea Spray for Cats cutaneous spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s)	% w/v
Pyrethrum Pale Extract 25%.....	0.882
(Equivalent to Pyrethrins.....)	0.221)
Piperonyl butoxide (100%).....	1.105

Excipient(s):

Butylated hydroxytoluene (BHT)..... 0.18

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cutaneous spray solution.
Pale yellow, mobile liquid with characteristic odour.

4. CLINICAL PARTICULARS

4.1 Target species

Cat

4.2 Indications for use, specifying the target species

To kill fleas on cats and kittens over 12 weeks of age and weighing more than 1.5kg.

4.3 Contraindications

- i) Do not use on kittens under 12 weeks of age or cats under 1.5kg, or on nursing females.
- ii) Do not spray on inflamed or broken skin.

4.4 Special warnings for each target species

Cats permitted to self-groom immediately post dosing and where excess spray has not been removed by towelling, may exhibit excessive salivation, which is usually transient and considered to be due to irritation of the oral mucosa.

4.5 Special precautions for use

i. Special precautions for use in animals

- a) Keep treated animals away from fires and other sources of heat for at least 30 minutes following spraying and until the fur is totally dry.

- b) For external use only.
- c) Discontinue use if skin condition deteriorates and seek veterinary advice.

ii. **Special precautions for the person administering the veterinary medicinal product to animals**

Highly flammable. Do not spray on a naked flame or on incandescent material. Do not smoke when using this product. Do not breathe spray mist and use in well ventilated area.

Avoid contact with eyes. In case of accidental eye contact, rinse with clean, fresh water. If eye irritation persists, seek medical advice.

Wash hands and exposed skin after use.

Persons who are hypersensitive (allergic) to pyrethrum extract should handle the product with care.

Treated animals should not be allowed to sleep or play with people, particularly children, until the animal is dry.

Keep away from food and drink, including animal feeding stuffs.

4.6 Adverse reactions (frequency and seriousness)

Cats permitted to self-groom immediately post dosing, and where excess spray has not been removed by towelling, may exhibit excessive salivation, which is usually transient and considered to be due to irritation of the oral mucosa.

4.7 Use during pregnancy, lactation or lay

- a) See section 4.3 above.
- b) Remove fleas from young kittens and nursing females by careful use of a flea comb.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

For cats and kittens over 12 weeks old and over 1.5kg bodyweight.

Groom your pet's fur in the wrong direction and then spray the coat from a distance of 30cm (12 inches). Gradually work from your cat's tail to the head. Avoid eyes and other sensitive areas. Each pump activation delivers 0.7ml of spray (1.5mg pyrethrins and 7.5mg piperonyl butoxide). For adult cats about 4kg (8lb 8oz) or above, use 16 pumps of spray. For kittens of at least 12 weeks of age, and cats weighing below 4kg, weigh the cat and then apply 4 pumps for every 1kg (2lb 3oz) of bodyweight. Brush the coat back into place and towel gently to remove excess spray. Do not allow the cat to groom until the coat has been towelled and appears dry. Re-apply when necessary, but allow at least 72 hours between applications.

This pack contains approximately 11 treatments for an adult cat.

Fleas from pets often infest animal's basket, bedding and regular resting areas such as carpets and soft furnishings should be treated with a suitable insecticide and vacuumed regularly.

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

Signs of pyrethrins poisoning include hyperaesthesia, involuntary muscular twitching, breathing difficulties, lethargy and salivation. For dermal exposure, wash with detergent and cold water. Activated charcoal can be used following oral ingestion of large quantities of the product. Otherwise, treatment is symptomatic. (NB: For overdosed cats exhibiting prolonged periods of salivation, ensure adequate supplies of fresh drinking water are available to avoid dehydration).

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides, insecticides and repellents, Ectoparasiticides for topical use, incl. Insecticides, Pyrethrins and pyrethroids.

ATC Vet Code: QP53AC30

5.1 Pharmacodynamic properties

The pyrethrins are potent, non-systemic, contact insecticides causing a rapid paralysis or "knockdown", death occurring at a later stage. Their mechanism of action is considered to involve inhibition of the inactivation of sodium channels and the activation of potassium conductance at the neurone axon level. This results in prolonged action potentials, repetitive neuronal firing after a single stimulus and spontaneous trains of action potentials.

5.2 Pharmacokinetic properties

The insecticidal activity of the pyrethrins is markedly enhanced by the inclusion of cytochrome P450 inhibitors which decrease their rate of metabolism by the insects; piperonyl butoxide is a methylenedioxyphenol synergist for pyrethrins and related insecticides and is included in the formulation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated Hydroxytoluene
Isopropyl Alcohol
Arlamol E
Water Potable

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

- i) Do not store above 25°C. Protect from light.
- ii) Keep away from food and drink.

6.5 Nature and composition of immediate packaging

145ml White high density polyethylene pump spray bottle with pump spray valve assembly.

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

Harmful to fish and crustaceans. Do not contaminate aquaria or fish bowls with the product. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bob Martin (UK) Ltd
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BS49 4BS

8. MARKETING AUTHORISATION NUMBER

Vm 00715/4047

9. DATE OF THE FIRST AUTHORISATION, OR DATE OF RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 October 1991

10. DATE OF REVISION OF THE TEXT

February 2010

Revised: February 2010
(Amended ATCVet code)