

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT:

Bob Martin Flea Spray for Dogs & Puppies cutaneous spray solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Active Substance(s)	% w/v
Pyrethrum Extract 25% (equivalent to Pyrethrins)	1.28 0.32)
Piperonyl Butoxide (100%) (added as Piperonyl Butoxide)	1.57

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM:

*Cutaneous Spray Solution.
Clear, yellow solution of characteristic odour.*

4. CLINICAL PARTICULARS:

4.1 Target species

Dog

4.2 Indications for use, specifying the target species:

For the control of fleas on dogs and puppies over 12 weeks of age.

4.3 Contra-Indications:

- (i) Not for use in cases of known hypersensitivity.
- (ii) Do not use on puppies under 12 weeks of age.
- (iii) Do not use on nursing females.

4.4 Special warnings for each target species

For external use only.

4.5 Special precautions

i) Special precautions for use in animals

Keep treated animals away from fire and other sources of heat for at least 30 minutes following spraying and until fur is totally dry.

ii) Special precautions to be taken by the person administering the medicinal products to animals

Flammable.

Do not spray on a naked flame or on any incandescent material.

Do not smoke when using the product.

Do not breathe spray mist and use in a well ventilated area.

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

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.

Wash hands and exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

Rarely, dogs treated with the product may show a hypersensitivity reaction.

4.7 Use during pregnancy, lactation or lay

(i) See section 4.2 above.

(ii) Remove fleas from young puppies and nursing bitches by careful use of a flea comb.

4.8 Interaction with other medicinal products and other forms of Interaction

None known.

4.9 Amounts to be administered and administration route

Shake thoroughly before use. Comb or brush the animal's coat the wrong way and spray into the coat at a distance of about 30cm (12 inches) working from the rear to the head. Avoid eyes and other sensitive areas. Repeat the treatment after 3-4 days if any reinfestation is apparent.

Use 9 seconds of spray on a small dog (e.g. Terrier).

Use 15 seconds of spray on a medium size dog (e.g. Collie).

Use 23 seconds of spray on a large dog (e.g. Alsatian).

Fleas from pets often infect animals' baskets, bedding and regular resting areas such as carpets and soft furnishings which should be treated with a suitable insecticide and vacuumed regularly.

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

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

The pyrethrins are potent, non-systemic, contact insecticides causing a rapid 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.

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.

5.2 Pharmacokinetic properties

No specific pharmacokinetic studies have been performed with the product.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

Kerosene deodorant perfume 1136
Kerosene odourless
Propane/Isobutane/Butane 30 Propellant

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

- i) Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C.
- ii) Flammable.

6.5 Nature and composition of immediate packaging

- a) Nature of Container:
 - i) Primary container: Internally lacquered tin plate aerosol can.
 - ii) Closure/Dosing device: ARD PCA 38F valve and M8ST actuator.
- b) Contents: Pack size 150ml.

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

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

7. MARKETING AUTHORISATION HOLDER:

Bob Martin (UK) Ltd.
Wemberham Lane
Yatton
Somerset
BS49 4BS
U.K.

8. MARKETING AUTHORISATION NUMBER:

Vm 00715/4048

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

First authorised: 04 October 1991

10. DATE OF REVISION OF THE TEXT:

13 November 2008