

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10881/010/001**

Case No: 7005908

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

The Bob Martin Company

Wemberham Lane, Yatton, Somerset, BS49 4BS, United Kingdom

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Bob Martin Flea Spray cutaneous spray solution

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **16/12/2007**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Flea Spray cutaneous spray solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per container:

Active substances	% w/v
Pyrethrum Pale Extract 25%	1.28
<i>(equivalent to pyrethrins</i>	<i>0.32)</i>
Piperonyl butoxide (100 %)	1.57

(added as Piperonyl Butoxide)

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Spray Solution

Clear, yellow solution of characteristic colour

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

For the control of fleas on dogs.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use on puppies under 12 weeks of age.

Do not use on nursing bitches.

4.4 Special warnings for each target species

For external use only.

4.5 Special precautions for use

Special precautions for use in animals

If signs of disease persist or appear, consult your veterinary surgeon/practitioner.

Sick and convalescing animals should be treated by a veterinary surgeon.

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

Special Precautions to be taken by the Person Administering the Medicinal Product 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

Do not use on nursing females.

Remove fleas from young puppies 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 Amounts to be administered and administration route

Shake thoroughly before use. Comb the animal's coat the wrong way and spray into the coat at a distance of about 30cm (12 inches) working from the rear of the head. Avoid eyes and other sensitive areas. Repeat 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 infest 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, antidotes), if necessary

The toxicity of pyrethrins and piperonyl butoxide to dogs is low, by both oral and percutaneous routes. However, in sensitive animals, overdose may elicit symptoms such as hyperaesthesia, muscle fasciculations, convulsions, salivation, pyrexia or hypothermia. Such signs are more likely in cats treated “off label” with the product. Occasionally, skin hypersensitivity may be observed, particularly where the animal has previously been exposed to crude extracts of pyrethrum.

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; there is no specific antidote. In animals convulsing, or with extreme CNS excitation, measures should be taken to minimise environmental stimuli during the period of emergency treatment.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, pyrethrins

ATCvet Code: QP53AC51

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.

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

Odourless Kerosene
Kerosene Deodorant Perfume
Butane 30

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.

6.4 Special precautions for storage

Pressurised container: Protect from sunlight and do not expose to temperatures exceeding 50°C.
Flammable.

6.5 Nature and composition of immediate packaging

150 ml internally lacquered tin plate aerosol can with valve and actuator.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not pierce or burn even after use.

Empty container thoroughly. Any unused product or waste material should be disposed of in accordance with national requirements.

Harmful to fish, crustaceans and reptiles - do not contaminate aquaria, fish bowls, etc.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10881/010/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th December 2007

10 DATE OF REVISION OF THE TEXT