

**IRISH MEDICINES BOARD ACT 1995**

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

**(S.I. No. 786 of 2007)**

VPA: **10881/007/001**

Case No: 7001032

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 Powder for Dogs and Cats**

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 **22/03/2006**.

Signed on behalf of the Irish Medicines Board

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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 Powder for Dogs and Cats

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active substances:</u>	<u>% w/w</u>
Pyrethrum powder 1.3% (equivalent to pyrethrins 0.10%)	7.78
Piperonal butoxide	0.80

#### Excipients:

Butylated Hydroxy Toluene	0.05
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For a full list of excipients, see Section 6.1.

#### 3 PHARMACEUTICAL FORM

Topical powder.  
A brownish-yellow powder.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Dogs and cats.

##### 4.2 Indications for use, specifying the target species

To kill fleas on dogs and cats over 12 weeks of age.

##### 4.3 Contraindications

Do not use on puppies or kittens under 12 weeks of age.

Do not use on nursing bitches or queens.

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

##### 4.4 Special warnings for each target species

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

## **4.5 Special precautions for use**

### **Special precautions for use in animals**

For external use only.

Avoid the animals's eyes.

### **Special precautions to be taken by the person administering the product to animals**

Avoid inhalation of powder.

Wash hands after use.

Avoid contact with eyes. In case of accidental eye contact, wash eyes with copious amounts of water. If irritation persists, seek medical advice.

Keep away from food, drink and animal feeding stuff

Persons with known hypersensitivity to compounds in the product should not handle the product.

Must be used in a well ventilated area..

## **4.6 Adverse reactions (frequency and seriousness)**

None known.

## **4.7 Use during pregnancy, lactation or lay**

Do not use on nursing bitches or queens.

## **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

## **4.9 Amounts to be administered and administration route**

Apply only when the coat is dry. Stand the animal on a sheet of paper or outdoors and comb or brush the coat the wrong way. Apply powder close to the skin. Brush excess powder off the coat, taking care to avoid the eyes and other sensitive areas. Brush out the coat after 30 minutes and do not allow the animal to groom itself until this has been done. Repeat the treatment weekly if reinfestation is apparent.

The amount of powder to use depends on the animal's size. An adult cat or small dog (e.g. terrier) will require 5-10g powder, the pack containing sufficient for 10-20 applications. A medium size dog (e.g. Collie) will require 10-15g powder, the pack containing sufficient for 6-10 applications. A large dog (e.g. Alsatian) will require 15-20g powder, the pack containing sufficient for 5-6 applications.

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.

Remove fleas from young puppies, kittens, nursing bitches or queens by careful use of a flea comb.

#### **4.10 Overdose (symptoms, emergency procedures, 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 or IMMUNOLOGICAL 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 P<sub>450</sub> 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 Hydroxy Toluene  
Magnesium Carbonate Light  
Perfume BM 1136  
Sipernat 5OS  
Talc substitute (XF Delafila)

#### **6.2 Incompatibilities**

None known.

#### **6.3 Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

#### **6.4 Special precautions for storage**

Store below 25°C.  
Protect from direct sunlight.  
Store in a dry place.  
Keep away from food and drink.

#### **6.5 Nature and composition of immediate packaging**

Primary container: Cylindrical white polypropylene tube.  
Closure: Polypropylene cap with hinged lid.  
Pack size: 100 g

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

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

Harmful to fish and crustaceans. Do not contaminate aquaria, fish bowls, etc.

## **7 MARKETING AUTHORISATION HOLDER**

The Bob Martin Company  
Wemberham Lane  
Yatton  
Somerset  
BS49 4BS  
U.K.

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA: 10881/007/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

22nd March 2006

## **10 DATE OF REVISION OF THE TEXT**