

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Flea Shampoo for Dogs & Puppies 1.9 mg/g / 4.9 mg/g

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	mg/g
Pyrethrum Extract 25%	1.9
(equivalent to Pyrethrins	0.475)
Piperonyl Butoxide	4.9
Excipients	
Bronopol	0.2
Hexablend WS Yellow 66889	0.154
(as Tartrazine E102 &	0.149
Carmoisine E122	0.05)

For a full list of excipients, see Section 6.1

### 3 PHARMACEUTICAL FORM

Shampoo.

A clear, orange-coloured viscous liquid.

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Dog.

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

For the control of fleas on dogs.

#### 4.3 Contraindications

- i) Do not use on cats.
- ii) Do not use on puppies under 12 weeks of age.
- iii) Do not use on nursing bitches.

#### 4.4 Special warnings for each target species

Not for use in dogs known to be hypersensitive.

## **4.5 Special precautions for use**

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

For external use only.

Avoid the animals eyes.

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

Wash hands and exposed skin after use.

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

Persons with known hypersensitivity (allergic reaction) to pyrethrum extract or other compounds in the product should not handle the product.

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

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

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

Adverse reactions are very rare.

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

(i) 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**

Mix the recommended amount of shampoo with 300ml of lukewarm water. Wet the dog's coat thoroughly with warm water and apply half the mixture. Massage well into the coat using fingertips around the head to avoid eyes, ears and mouth. Rinse and repeat with the remainder of the mixture working up to a good lather. Rinse well with lukewarm water and air dry. Keep dog indoors until completely dry.

Use 30ml shampoo for a small dog (e.g. Terrier)

Use 50ml shampoo for a medium size dog (e.g. Collie).

Use 70ml shampoo for 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**

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**

### **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 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.

### **5.2 Pharmacokinetic properties**

No specific pharmacokinetic studies have been performed with the product.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Bronopol  
Hexablend WS Yellow 66889  
(as Tartrazine E102 and Carmoisine E122)  
Sodium lauryl ether sulphate  
Coconut diethanolamide  
Ethoxylated lanolin  
Fragrance Compound BM MOD 279156  
Sodium chloride  
Citric acid monohydrate  
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**

Do not store above 25°C. Protect from direct sunlight.  
Protect from frost.  
Keep away from food and drink and animal feeding stuffs.

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

150 and 250ml cylindrical polyvinyl chloride (PVC) bottle with 24mm, medium, domed, double-walled white polypropylene cap (bore seal).

Not all pack sizes may be marketed.

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

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 national requirements.

## **7 MARKETING AUTHORISATION HOLDER**

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

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

VPA 10881/008/001

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

Date of first authorisation: 23<sup>rd</sup> March 2001

Date of last renewal: 20<sup>th</sup> February 2009

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

June 2015