

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 the 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. Contra-Indications

Do not use on cats.

Do not use on puppies under 12 weeks of age.

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

- i) Special precautions for use in animals

For external use only.
Avoid the animals eyes
- ii) Special precautions to be taken by the person administering the veterinary medicinal 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

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 in to 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 dog (e.g. Collie)

Use 70ml 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, 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

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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.

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 derived from the use of such products

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
Wemberham Lane
Yatton
North Somerset
BS49 4BS

8. MARKETING AUTHORISATION NUMBER

Vm: 00715/4049

9. DATE OF THE FIRST AUTHORISATION

Date: 01 May 1992

10. DATE OF REVISION OF THE TEXT

Date: June 2015



Approved: 15 June 2015