

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Bob Martin Permethrin 1% w/w Flea Shampoo for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| Active Substance(s) | % w/w |
|----------------------------|--------------|
| Permethrin (Technical) | 1.000 |
| Cis:trans 40:60 | |

Excipients

| | |
|--|----------|
| Sodium Propyl Hydroxybenzoate..... | 0.100 |
| Phenoxyethanol..... | 0.800 |
| Green colourant..... | 0.005 |
| (As Green Colouring W178680 or Percol F731 | |
| Contributing : | |
| Patent blue (E131)..... | 0.0018 |
| Tartrazine (E102)..... | 0.0010 |
| Sunset Yellow (E110)..... | .0.0010) |

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Shampoo
Green viscous liquid

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 Contra-indications

- 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

Remove fleas from young puppies and from nursing females by careful use of a flea comb.

4.5 Special precautions for use

- i. Special Precautions for use in animals.

For external use only

Avoid contact with animal's eyes

Wash any containers used thoroughly

Fleas from pets often infect animals' baskets, bedding and regular resting areas such as carpets and soft furnishings. As part of a flea control programme these areas should also be treated with a suitable insecticide and vacuumed regularly.

- ii. Special Precautions to be taken by the person administering the medicinal product to animals

Avoid prolonged contact with the skin. It is advisable to wear gloves whilst using this product.

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

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)

There are no recorded undesirable effects for this product.

4.7 Use during pregnancy, lactation or lay

Do not use on nursing bitches.

4.8. Interaction with other medicinal products and other forms of interaction

There are no recorded cases of any interaction with other medicinal products.

4.9 Amounts to be administered and administration route

Topical

Dosage Schedule

Soak coat with warm water, apply about two-thirds of the shampoo, work in well avoiding eyes. Rinse, repeat application with the remaining volume of shampoo, working up lather. Rinse thoroughly. Dry with towel or hairdryer.

Dosage Levels

| | |
|---------------|------------|
| Small Breeds | 20 – 30 ml |
| Medium Breeds | 40 – 50 ml |
| Large Breeds | 50 – 60 ml |

Depending on the length of coat

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

There is very little likelihood of any acute overdosage

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATCvet Code: QP53AC04

5.1 Pharmacodynamic properties

Permethrin is well recognised as a veterinary insecticide and has actions and uses similar to those of pyrethrum flower. The synthetic pyrethroids exert their action by unbalancing the parasite nerve fibres causing initial excitement followed by paralysis. Permethrin acts as a contact insecticide with rapid knockdown effect and some repellence against the flea

5.2 Pharmacokinetic properties

Not applicable as this product is for topical use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Propyl Hydroxybenzoate

Phenoxyethanol

Green Colouring [containing Patent Blue V (E131), Tartrazine (E102), Sunset Yellow (E110) & Sodium Chloride]

Triethanolamine Lauryl Sulphate Solution
Coconut Diethanolamide
Perfume
Hydrogenated Castor Oil
Sodium Hydroxide (for pH adjustment)
Citric Acid (for pH adjustment)
Potable Water

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) Do not store above 25°C.
- ii) Protect from light.
- iii) Do not refrigerate.
- iv) Protect from direct sunlight.
- v) Protect from frost.

6.5 Nature and composition of immediate packaging

Bob Martin Permethrin 1% w/w Flea Shampoo for Dogs is packed in PVC or HDPE containers with high density polyethylene or polypropylene caps in 125 ml, 150 ml, 250 ml, 400 ml, 2, 2.25, 4, 4.5 and 22.5 litre sizes.

Not all pack sizes may be marketed.

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

EXTREMELY DANGEROUS 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

Pets Choice Limited
Brentwood House
Lower Philips Road
Whitebirk Industrial Estate
Blackburn
Lancashire
BB1 5UD
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 52797/4021

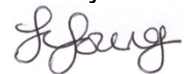
9. DATE OF THE FIRST AUTHORISATION

31 May 2001

10. DATE OF REVISION OF THE TEXT

May 2020

Approved: 29 May 2020

A handwritten signature in black ink, appearing to read 'J. Long', is written below the approval date.