

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Beaphar Insecticidal Shampoo for dogs, 10mg/g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Substance(s)</u>	<u>% w/w</u>
Permethrin (Technical)	1.000
Cis:trans 40:60	

Excipients

Sodium Propyl Hydroxybenzoate	0.100	Antimicrobial preservative
Phenoxyethanol	0.800	Antimicrobial preservative
Green colourant	0.005	Colourant

{**As** Green Colouring W178680 **OR** :

Percol F731 Colourant

[Containing Patent Blue (E131) , Tartrazine (E102),
Sunset Yellow ((E110) and Sodium Chloride)]

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 infest 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
SOS Bouquet 440860

Hydrogenated Castor Oil
Sodium Hydroxide 10%w/v (for pH adjustment)
Citric Acid Monohydrate 10%w/v (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

Beaphar Insecticidal Shampoo for dogs, 10mg/g 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

Harmful to fish and crustaceans. Do not contaminate aquaria or fish bowls with the product. Dispose of any waste water onto soil not used for growing vegetables.

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

Distributor:
Beaphar UK Ltd,
Rook Tree Farm,
Withersfield Road,
Great Wratting,
Suffolk
CB9 7HD.
United Kingdom

8. MARKETING AUTHORISATION NUMBERS

GB - Vm 52797/5010
NI - Vm 52797/3010

9. DATE OF THE FIRST AUTHORISATION

07 October 2024

10. DATE OF REVISION OF THE TEXT

October 2024

Gavin Hall
Approved: 07 October 2024