

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Beaphar Insecticidal Dog Shampoo, 0.2% w/w

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### Active substance

Permethrin (cis:trans 40:60)	0.2	% w/v
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### Excipients

Formaldehyde	0.0675	% w/v
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Patent blue V (E131)	0.00034	% w/v
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Quinoline yellow (E104)	0.00044	% w/v
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For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Shampoo

Bright green, clear shampoo

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dogs and puppies over 12 weeks of age.

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

For the control of fleas on dogs and puppies over 12 weeks of age.

### 4.3 Contraindications

Do not use on cats.

Do not use on puppies under 12 weeks of age.

Do not use on nursing females.

Do not use with other topically applied products.

Do not use on sick and convalescing animals.

Do not re-apply within 7 days of use.

### 4.4 Special warnings for each target species

To help prevent reinfestation, animal bedding, basket and regular resting areas (including carpets and soft furnishings) should be treated with a suitable insecticide and vacuumed regularly.

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

Sick and convalescing animals should be treated by a Veterinary Surgeon. If signs of disease persist or appear after treatment, consult a Veterinary Surgeon.

### 4.5 Special precautions for use

#### Special precaution(s) for use in animals

For external use only.

Avoid contact with the eyes, nostrils and mouth.

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

This product contains formaldehyde.

Avoid contact with skin. Wear protective gloves when applying the product to your dog and wash any 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.

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.

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

Skin irritation to the 40:60 cis:trans isomer may occur in sensitive individuals.

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

Do not use on nursing females.

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

Do not use concurrently with other topical insecticides.

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

Wet the coat thoroughly with warm water using the following dosing levels:

**Small Dogs** (1.5 – 5.0 kg) 30 ml of shampoo diluted into 300 ml of warm water.

**Medium Dogs** (5.1 – 15.0 kg) 50 ml of shampoo diluted into 300 ml of warm water.

**Large Dogs** (15.1 – 30.0 kg) 70 ml of shampoo diluted into 300 ml of warm water.

Pour diluted dose carefully over dog in small quantities and work well into coat, avoiding eyes, nostrils and mouth. Rinse thoroughly with clean water after two minutes, during which time the dog should be held.

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

Symptoms: Nausea, vomiting, general weakness.

Skin irritation may occur in sensitive individuals.

Emergency procedures: Consult a Veterinary Surgeon.

In case of skin irritation, wash immediately with plenty of water.

In case of ingestion, carry out gastric lavage.

No specific antidote is known.

Treatment should be symptomatic and supportive.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Ectoparasitocides for topical use, incl. insecticides

ATCvet Code: QP53AC04

#### **5.1 Pharmacodynamic properties**

Permethrin is a non-systemic insecticide with contact and stomach action. It acts on sodium channels of parasite nerve axons causing initial excitement then paralysis and death.

#### **5.2 Pharmacokinetic particulars**

Mammalian toxicity is very low. The 40:60 cis:trans isomer of permethrin can have greater irritancy.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Formaldehyde  
Patent blue V (E131)  
Quinoline yellow (E104)  
Sodium lauryl ether sulphate  
Nonoxinol 6  
Industrial methylated spirit  
Perfume Solexia 2090GB  
Perfume Ambrene  
Purified water

### **6.2 Major 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**

Protect from frost.  
Protect from direct sunlight. Do not store above 25°C.

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

Pack size: 100 ml / 250 ml

Container: Clear, colourless PVC bottle

Closures: Polypropylene or urea formaldehyde screw cap.

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**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Harmful to fish and crustaceans. Do not contaminate aquaria or fish bowls with the product.

**7 MARKETING AUTHORISATION HOLDER**

Beaphar B.V.  
Drostenkamp 3  
PO Box 7  
8100 AA Raalte  
Netherlands

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA10455/004/001

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

Date of first authorisation: 01 October 1989  
Date of last renewal: 30 September 2009

**10 DATE OF REVISION OF THE TEXT**

March 2019