

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Beaphar Insecticidal Dog Shampoo, 0.2% w/w.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

<u>Active substance</u>	<u>% w/w</u>
Permethrin (cis:trans 40:60)	0.2

<u>Excipients</u>	<u>% w/w</u>
Formaldehyde	0.0675
Patent Blue V (E131)	0.00034
Quinoline Yellow (E104)	0.00044

For 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 Contra-indications**

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 re-infestation, 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

i. Special precautions for use in animals

For external use only.

Avoid contact with the eyes, nostrils and mouth.

ii. Special precautions to be taken by the person administering the 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 interaction

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:

<b>Small Dogs</b>	(1.5 - 5.0 kg)	30 ml of shampoo diluted into 300 ml of warm water.
<b>Medium Dogs</b>	(5.1 -15.0 kg)	50 ml of shampoo diluted into 300 ml of warm water.
<b>Large Dogs</b>	(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 PROPERTIES**

**Pharmacotherapeutic group:** Ectoparasiticides 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 Spirits  
Perfume Solexia 2090 GB  
Perfume Ambrene  
Water Purified

#### **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**

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, if appropriate**

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 UK Ltd  
Rook Tree Farm  
Withersfield Road  
Great Wratting  
Suffolk  
CB9 7HD

## **8. MARKETING AUTHORISATION NUMBER**

Vm 13907/4013

## **9. DATE OF FIRST AUTHORISATION**

9 January 1996

## **10. DATE OF REVISION OF TEXT**

June 2018

Revised: June 2018  
AN: 00192/2018

Approved: 07 June 2018

A handwritten signature in black ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending from the end of the name.