

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Beaphar Worming Granules for Dogs and Puppies, 666 mg/sachet

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

<u>Active substance</u>	<u>mg/sachet</u>
Fenbendazole	666

For full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Granules  
Free flowing, white to greyish white, granular powder.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs

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

Treatment of immature and mature stages of common roundworms of domestic dogs.  
The product also has an ovicidal effect on nematode eggs.

#### **4.3 Contra-indications**

None known.

#### **4.4 Special warnings for each target species**

Seek the advice of a veterinary surgeon for the treatment of pregnant dogs.

#### **4.5 Special precautions for use**

i. Special precautions for use in animals

Not for the treatment of puppies weighing less than 6.5 kg or adult dogs weighing less than 3.3 kg.

Assess body weight of dogs as accurately as possible before calculating the dosage.

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

Direct contact with the skin should be kept to a minimum.  
Avoid the inhalation of dust.  
Wash hands after use.

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

None known.

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

Not recommended.

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

Not applicable.

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

For oral administration only, sprinkled onto food or by mouth.

Not for the treatment of puppies weighing less than 6.6 kg or adult dogs weighing less than 3.3 kg

For the treatment of puppies over 12 weeks but under 6 months and weighing at least 6.6 kg, give the following recommended number of sachets EACH DAY for 3 CONSECUTIVE DAYS:

6.6 to 13.2 kg	(15 to 30lb)	1 sachet
13.3 to 26.4 kg	(30.1 to 60lb)	2 sachets

Very small or unweaned puppies up to 12 weeks of age should be treated with a suitable product.

For the routine treatment of adult dogs (over 24 weeks), treat every 3-6 months. A dosage of 100 mg Fenbendazole per kg bodyweight is recommended. Give the following recommended number of sachets as a SINGLE dose:

3.3 to 6.6 kg	(7.5 to 15lb)	1 sachet
6.7 to 13.2 kg	(15.1 to 30lb)	2 sachets
13.3 to 19.8 kg	(30.1 to 45lb)	3 sachets
19.9 to 26.4 kg	(45.1 to 60lb)	4 sachets

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

Benzimidazoles have a wide safety margin.

**4.11 Withdrawal period(s)**

Not applicable.

**5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Anthelmintics

**ATCvet code:** QP52AC13

## **5.1 Pharmacodynamic properties**

Fenbendazole is a member of the benzimidazole family of anthelmintics. Fenbendazole acts against parasites by disrupting the formation of microtubules by binding to tubulin in parasitic intestinal cells, preventing the absorption of glucose. Parasites are gradually starved to death.

## **5.2 Pharmacokinetic particulars**

Fenbendazole displays preference for parasitic as opposed to mammalian tubulin. It appears that the formation of the parasitic tubulin-fenbendazole complex is more favourable kinetically under physiological conditions than the mammalian complex.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactose monohydrate  
Povidone K30  
Sodium lauryl sulphate

### **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**

Store in a dry place.  
Add to feed immediately before administration.  
Discard any remaining medicated feed.

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

3 g of product contained in a paper/low density polyethylene/foil/low density polyethylene sachet.

### **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.

## **7. MARKETING AUTHORISATION HOLDER**

Sinclair Animal and Household Care Ltd.  
Ropery Road  
Gainsborough  
Lincolnshire  
DN21 2QB

**8. MARKETING AUTHORISATION NUMBER**

**Vm** 16516/4025

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

Date of first authorisation: 8 January 2002  
Renewal of the authorisation: 8 January 2007

**10. DATE OF REVISION OF THE TEXT**

January 2010