

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Panacur Equine Guard with Apple and Cinnamon Flavour  
10% w/v Oral Suspension

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

Each 225 ml bottle contains:

<u>Active substance(s)</u>	% w/v
Fenbendazole	10.000
<u>Excipients</u>	
Sodium Methyl Parahydroxybenzoate	0.200
Sodium Propyl Parahydroxybenzoate	0.020

For full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Oral Suspension.  
A white, aqueous suspension.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Horses and other equines.

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

For the treatment and control of adult and immature roundworms of the gastro-intestinal tract in horses and other equines.

The product is also effective for the treatment and control of encysted mucosal 3rd and 4th stage small strongyle larvae and is also effective against encysted inhibited 3rd stage small strongyle larvae in the mucosa.

It is also effective in controlling other immature and mature roundworms including large redworm (*Strongylus edentatus* and *Strongylus vulgaris*) and migrating large redworm, *Ascarids* (*Parascaris equorum*), *Oxyuris* and *Strongyloides* species and benzimidazole susceptible adult and immature small strongyles (Cyathostomes).

Fenbendazole also has an ovicidal effect on nematode eggs.

### **4.3 Contra-indications**

None known.

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

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Under dosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any)

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to fenbendazole has been reported in cyathostomes in horses. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

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

- i. Special precautions for use in animals

Assess bodyweight as accurately as possible before calculating the dosage.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

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

Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves.

Wash hands after use.

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

None known.

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

Pregnant mares and young foals may also be safely treated with fenbendazole at therapeutic dosage levels.

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

None known.

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

Shake container before use.

No dietary control is required before or after treatment.

For the treatment and control of migrating and tissue larval stages of large strongyles, encysted mucosal 3rd and 4th stage small strongyle larvae and encysted inhibited 3rd stage small strongyle larvae in the mucosa administer 5 ml. per 65 kg bodyweight daily for 5 days (= 7.5 mg fenbendazole/kg bodyweight daily for 5 days).

The product can be easily administered by mixing with grain or concentrate feed.

The full daily dosage must be given as one administration.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

##### Recommended dosing programme

Treatment of encysted inhibited and encysted mucosal dwelling larvae should be carried out in the autumn (ideally late October/November) and again in the Spring (ideally in February). However, for horses that fail to maintain condition or bought-in horses with unknown worming history, the treatment can be given at any time of the year.

Treatment with the product should form part of an integrated worming plan. Consult with your supplier for advice regarding wormers to use throughout the year.

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

Benzimidazoles have a wide margin of safety.

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

Not to be used in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Fenbendazole is an anthelmintic belonging to the benzimidazole carbamates group. It acts by interfering in the energy metabolism of the nematode. The anthelmintic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli. The anthelmintic affects both adult and immature stages of gastro-intestinal and respiratory nematodes.

**ATC Vet Code:** QP52AC13

### **5.2 Pharmacokinetic particulars**

Fenbendazole is only partly absorbed from the intestine and reaches maximum plasma concentration 6 (4-8) hours after oral administration. Fenbendazole is metabolised mainly by enzymes of the cytochrome P -450 system in the liver.

The major oxidative metabolite is fenbendazole sulfoxide which is further metabolised to fenbendazole sulfone.

Fenbendazole and its metabolites are distributed throughout the body but highest concentrations are found in the liver.

Fenbendazole and its metabolites are detectable in the plasma only during the first 48 hours following drug administration at a single dose rate of 10 mg fenbendazole/ kg bodyweight.

Administration of fenbendazole at a dose rate of 10 mg/kg bodyweight daily for five consecutive days lead to accumulation of fenbendazole during the multiple dosing period whereas the concentrations of its two metabolites show only a slight increase. After the last administration on day 5, all three compounds are eliminated from blood very rapidly, within two or three days.

The elimination of fenbendazole and its metabolites occurs primarily via the faeces.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium Methyl Parahydroxybenzoate  
Sodium Propyl Parahydroxybenzoate  
Apple and Cinnamon Flavour (Ref no. 216267)  
Silica colloidal anhydrous  
Carmellose sodium  
Povidone K25  
Sodium Citrate dihydrate

Citric Acid Monohydrate  
Water Purified

**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**

Protect from freezing.

**6.5 Nature and composition of immediate packaging**

A 225ml, multidose, opaque, white high density polyethylene bottle. The closure is tamper proof with an aluminium foil seal and a polypropylene cap (screw-fit).

**6.6 Special precautions for the disposal of unused veterinary medicinal product 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.

Dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with product or used container.

**7. MARKETING AUTHORISATION HOLDER**

MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ

**8. MARKETING AUTHORISATION NUMBER**

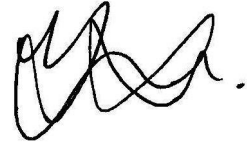
Vm 01708/4441

**9. DATE OF FIRST AUTHORISATION**

07 October 1998

**10. DATE OF REVISION OF TEXT**

December 2020

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 30 December 2020