SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Guard 10% w/v Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):	% w/v
Fenbendazole	10.000
Excipients	
Sodium Methyl Parahydroxybenzoate	0.200
Sodium Propyl Parahydroxybenzoate	0.0216
Benzyl Alcohol	0.4835

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 strogyle larvae in the mucosa.

The product 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).

The product 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

For oral administration.
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 Of the product 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 performed 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.

Shake container before use.

Treatment with this 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-carbamate group. It acts by interfering with the energy metabolism of the nematode.

The anthelmintic affects both adult and immature stages of gastro-intestinal and respiratory nematodes. This anthelmintic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli.

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5.2 Pharmacokinetic properties

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
Benzyl alcohol
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: 2 years.

6.4 Special precautions for storage

Do not freeze

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 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 the 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

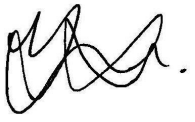
Vm 01708/4466

9. DATE OF FIRST AUTHORISATION

5 September 2000

10. DATE OF REVISION OF TEXT

December 2020



Approved: 30 December 2020