SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Granules 22.2% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Qualitative composition	Quantitiative composition % w/w
Fenbendazole	22.222

Excipients
For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Granules
A white to yellowish-white granular powder.

4. CLINICAL PARTICULARS

4.1 Target species

Horses and other equines.

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for the treatment and control of adult and immature roundworms of the gastro-intestinal tract in horses and other equines.

Panacur effectively treats and controls the following roundworm infections:
Large strongyles (adults and migrating larval stages of *S.vulgaris*; adults and tissue larval stages of *S. edentatus*)
Adult and immature small strongyles (Cyathostomes) (benzimidazole susceptible) including encysted mucosal 3rd and 4th stage larvae; it is also effective against inhibited 3rd stage larvae (encysted) in the mucosa.
Adult and immature *Oxyuris spp., Strongyloides spp.* and *Parascaris equorum.*

Panacur 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.

(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. Avoid inhalation of granule dust. 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 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

Routine treatment: Administer orally 5g Panacur Equine Granules per 150kg bodyweight. (= 7.5mg fenbendazole/kg bodyweight)

Practical dosage recommendations:

Up to 150kg	5g
151 to 300kg	10g
301 to 450kg	15g
451 to 600kg	20g
601 to 750kg	25g
751 to 900kg	30g

Panacur Equine Granules sachet packs each contain 10.2g granules and can be used as follows:

Foals and ponies up to 300kg bodyweight	1 sachet
Thoroughbreds and other breeds of horses up to 600kg bodyweight	2 sachets
Heavy hunters, heavy draft horses	3 sachets
Donkeys	1 sachet

Increased dosing for specific infections

Five day course:
For the treatment and control of migrating larval stages of large strongyles and encysted mucosal 3rd and 4th stage larvae and inhibited 3rd stage small strongyle larvae (encysted) in the mucosa, administer 5g Panacur Equine Granules per 150kg bodyweight daily for 5 days.
(= 7.5mg fenbendazole/kg bodyweight daily for 5 days)

Single dose treatments:
For the treatment and control of encysted mucosal stages of small strongyles, administer 20g Panacur Equine Granules per 150kg bodyweight.
(= 30mg fenbendazole/kg bodyweight)

For the treatment and control of migrating stages of large strongyles, administer 40g Panacur Equine Granules per 150kg bodyweight.
(= 60mg fenbendazole/kg bodyweight)

Diarrhoea caused by *Strongyloides westeri* in two to three week old suckling foals should be treated with Panacur 10% Suspension at a dose rate of 25ml per 50kg bodyweight.
(= 50mg fenbendazole per kg bodyweight)

Panacur Equine Granules should be sprinkled onto concentrate or grain feed and the full dosage 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
All horses should be routinely wormed with the single dose of Panacur Equine Granules every 6-8 weeks.
Treatment of encysted mucosal dwelling larvae should ideally be done in the autumn (late October/November) and again in the Spring.
However, for horses who fail to maintain condition or bought-in horses with unknown worming history, the treatment can be given at any time of the year.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
Benzimidazoles are unlikely to cause any reactions in the target species.

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

Lactose monohydrate
Povidone 2500
Maize starch

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Pack A:
A 10 g low density polyethylene/aluminium foil/paper laminated sachet with heat sealed closure, contained in a secondary cardboard box, consisting of either 10 or 100 sachets per box.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

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

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

8. MARKETING AUTHORISATION NUMBER

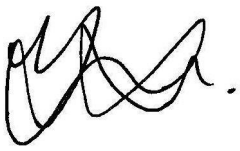
Vm 01708/4424

9. DATE OF FIRST AUTHORISATION

29 January 1993

10. DATE OF REVISION OF TEXT

December 2020



Approved: 30 December 2020