SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine 222 mg/g Granules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Fenbendazole 222 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Povidone 2500 (synonym to Povidone K25)
Maize starch

A white to yellowish-white granular powder.

3. CLINICAL INFORMATION

3.1 Target species

Horses and other equines.

3.2 Indications for use for each target species

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

The veterinary medicinal product 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*).
Benzimidazole susceptible adult and immature small strongyles (cyathostomes) including encysted mucosal 3rd and 4th stage larvae and it is also effective against inhibited 3rd stage larvae (encysted) in the mucosa.

Adult and immature *Oxyuris* spp., *Strongyloides* spp. and *Parascaris equorum*.

This veterinary medicinal product has an ovicidal effect on nematode eggs.

3.3 Contraindications

None known.

3.4 Special warnings

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.
- Underdosing, which may be due to underestimation of bodyweight, misadministration of the veterinary medicinal 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 veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Direct contact with the skin should be kept to a minimum. Avoid inhalation of granule dust. Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses and other equids:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended. Accuracy of the dosing device should be checked.
The veterinary medicinal product should be sprinkled onto concentrate or grain feed and the full dosage given as one administration. It is not necessary to withhold feed before or after treatment.

Routine treatment: Administer orally 5 g of the veterinary medicinal product per 150 kg bodyweight.
(= 7.5mg fenbendazole/kg bodyweight)

Practical dosage recommendations:

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

Each sachet contains 10.2 g granules and can be used as follows:

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

<u>Increased dosing for specific infections</u>
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 5 g of the veterinary medicinal product per 150 kg bodyweight daily for 5 consecutive days.
(= 7.5 mg fenbendazole/kg bodyweight daily for 5 days)

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

For the treatment and control of migrating stages of large strongyles, administer 40 g of the veterinary medicinal product per 150 kg bodyweight.

(= 60 mg 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 25 ml per 50 kg bodyweight.
(= 50 mg fenbendazole/kg bodyweight)

Recommended dosing programme:
Inappropriate use of anthelmintics may increase resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on professional advice and take into account current best practice recommendations for parasite control.

Seek veterinary advice for appropriate monitoring, stock management and dosing programmes to allow optimum endoparasite control.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Benzimidazoles are unlikely to cause any reactions in the target species.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13

4.2 Pharmacodynamics

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 gastrointestinal and respiratory nematodes.

4.3 Pharmacokinetics

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.

Environmental properties
Fenbendazole is toxic to fish and other aquatic organisms.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

A 10.2 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.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or used container.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with

any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4092

8. DATE OF FIRST AUTHORISATION

29 January 1993.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall

Approved 22 February 2026