SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Oral Paste 18.75% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 24g syringe contains:

Active substance(s)	% w/w
Fenbendazole	18.75
Excipient(s)	
Methyl Parahydroxybenzoate	0.17
Propyl Parahydroxybenzoate	0.016

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral paste.
A white to light grey homogenous paste.

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 also has an ovicidal effect on nematode eggs.

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*).

Benzimidazole susceptible adult and immature small strongyles (Cyathostomes), including encysted mucosal 3rd and 4th stage larvae; it is also effective against encysted inhibited 3rd stage larvae in the mucosa.

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

4.3 Contraindications

None.

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.
Wear impermeable rubber gloves while administering the product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy or lactation

Pregnant mares and 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, 1 Syringe per 600 kg bodyweight
(= 7.5 mg fenbendazole/kg bodyweight)

Practical dosage recommendations:

Up to 100kg	Miniature ponies	Syringe mark 100kg
101 to 300kg	Donkey, shetland and other small ponies & foals	Syringe mark 300kg (½ syringe)
301 to 400kg	Dartmoor, New Forest, *Welsh*	Syringe mark 400kg
401 to 500kg	Light hunters, Arabs etc	Syringe mark 500kg
501 to 600kg	Thoroughbreds	Syringe mark 600kg (1 syringe)
601kg and over	Heavy hunters, draught horses	1 full syringe plus additional 100kg syringe marks for each extra 100kg bodyweight

Increased dosing for specific infections:
Five day course:
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 1 syringe per 600 kg bodyweight daily for 5 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 1 syringe per 150 kg bodyweight.
(= 30 mg fenbendazole/kg bodyweight)

For the treatment and control of migrating stages of large strongyles administer 1 syringe per 75 kg bodyweight.
(= 60 mg fenbendazole/kg bodyweight)

For the treatment and control of Strongyloides westeri in sucking foals administer 1 syringe per 90 kg bodyweight.
(= 50 mg fenbendazole/kg bodyweight)

Panacur Equine Paste should be administered orally by squeezing the paste from the syringe onto the back of the tongue. No dietary control is required before or after treatment.

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 Paste every 6-8 weeks.
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 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 have a high margin of safety.

4.11 Withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero

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

ATCvet code: QP52AC13

Fenbendazole 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.

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

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Propylene Glycol
Apple and Cinnamon Flavour
Carbomer 980
Glycerol (85%)
Sorbitol (70%, crystalising)
Sodium Hydroxide
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

Do not store above 25˚C. Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

A 24g, white, opaque, high density polyethylene, graduated oral syringe with a low density polyethylene plunger and plunger head. The closure is a white, opaque, low density polyethylene cap (push-fit).

6.6 Special precautions for 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

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4094

9. DATE OF FIRST AUTHORISATION

29 January 1993

10. DATE OF REVISION OF TEXT

November 2024

Gavin Hall
Approved: 22 November 2024