1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine 187.5 mg/g Oral Paste

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1g of oral paste contains:

Active substance:
Fenbendazole 187.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl Parahydroxybenzoate	1.7 mg
Propyl Parahydroxybenzoate	0.16 mg
Mono Propylene Glycol	
Apple cinnamon flavour	
Carbomer 980	
Glycerol (85%)	
Sorbitol, liquid crystalising	
Sodium Hydroxide	
Water Purified	

A white to light grey homogenous paste.

3. CLINICAL INFORMATION

3.1 Target species

Horses and other equine species.

3.2 Indications for use for each target species

For the treatment of immature and mature stages of nematodes of the gastro-intestinal tract of horses and other equine species.

Sensitive endoparasites include adult and immature stages of:
Large and small strongyles
Ascarids
Oxyuris equi
Strongyloides spp.
Dictyocaulus arnfeldi

The veterinary medicinal product is effective for the treatment of immature and migrating strongyle infections in equines.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

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.
- Under dosing, which may be due to underestimation of body weight, misadministration of the veterinary medicinal product, or lack of calibration of the dosing device.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing.

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. Personal protective equipment consisting of protective clothing and impermeable rubber gloves should be worn when handling the veterinary medicinal product. Wash hands after use.

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

3.6 Adverse events

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 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 and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral administration only.

The recommended dosage is 7.5 mg FBZ/kg b.w. corresponding to 24 g (contents of 1 syringe) for 600 kg b.w.

Diarrhoea caused by *Strongyloides westeri* in sucking foals should be treated with a dose of 50 mg FBZ/kg b.w. corresponding to 24 g (1 syringe) for 90 kg b.w.

For the treatment of mucosal stages of *Trichonema* spp. (small strongyles) infestations the recommended dosage rate is 30 mg/kg. For the treatment of migrating stages of *Strongylus vulgaris* and *Strongylus edentatus* infestations the recommended dosage rate is 60 mg/kg.

Alternatively, 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 five days.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

No specific overdose reactions known.

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

Meat and offal: 14 days.
Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Fenbendazole is only partly absorbed after oral administration and is then metabolised in the liver. The half-life of FBZ in serum after oral application of the recommended dose is 10 - 18 hours in cattle, 21 - 33 hours in sheep and 10 hours in pigs. FBZ and its metabolites are distributed throughout the body but highest concentrations are found in the liver. The elimination of fenbendazole and its metabolites occurs primarily via the faeces (>90 %) and to a smaller extent in the urine and milk.

Fenbendazole is metabolised to its sulfoxide, then to sulfone and amines.

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.

Once opened use immediately.

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

White opaque metered polyethylene syringe, push-fit cap and adjusting ring containing 24 g of the veterinary medicinal product. The body of the syringe is made of high density polyethylene (HDPE). The push-fit cap is composed of low density polyethylene as is the plunger rod and plunger head. The metering device is made of HDPE. 10 or 20 syringes per carton.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.

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 Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/118/001

8. DATE OF FIRST AUTHORISATION

01/10/1999

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

13/08/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).