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 g paste contains:

Active Substance	
Fenbendazole	187.5 mg
Excipients	
Methyl Parahydroxybenzoate	1.7 mg
Propyl Parahydroxybenzoate	0.16 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral paste.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses and other equine species

4.2 Indications for use, specifying the 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

Panacur is effective for the treatment of immature and migrating strongyle infections in equines.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings 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.
- Underdosing, which may be due to underestimation of body weight, misadministration of the 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.

4.5 Special precautions for use

Special precaution(s) for use in animals

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. 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, lactation or lay

Can be administered to animals at any stage of pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No interactions known.

4.9 Amounts to be administered and administration route

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 *Strongloides 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 administration of a correct dose, body weight should be determined as accurately as possible.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No specific overdose reactions known.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered during treatment.
Meat and offal: 14 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Benzimidazoles and related substances
ATCvet code: QP52AC13

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.

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 980
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Propylene Glycol
Glycerol (85 per cent)
Sorbitol 70 per cent (crystallising)
Sodium Hydroxide
Apple Cinnamon Flavour
Purified Water

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.

6.5 Nature and composition of immediate packaging

White opaque metered polyethylene syringe, push-fit cap and adjusting ring containing 24 g Panacur Paste. 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park
Citywest Road
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/118/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

22nd July 2011