1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 10 % w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active Substance		
Fenbendazole	100	mg
Excipients		
Sodium Methyl Parahydroxybenzoate	2.000	mg
Sodium Propyl Parahydroxybenzoate	0.216	mg
Benzyl alcohol	4.835	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Horses and cattle

4.2 Indications for use, specifying the target species

For the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts of cattle and horses including encysted mucosal small redworm larvae in horses. Panacur has an ovicidal effect on roundworm eggs. Also effective against cestodes in cattle.

For the treatment of horses infected with adult large strongyles and adult and larval small strongyles. Also controls ascarids and oxyurids species.

For the treatment of cattle infected with adult and immature stages of: *Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp., *Cooperia* spp., *Nematodirus* spp., *Bunostomum* spp., *Trichuris* spp., *Strongyloides* spp., *Oesophagostomum* spp., *Capillaria* spp., *Dictyocaulus* spp.

Used at the recommended dose and time, Panacur is effective against inhibited larvae of *Ostertagia* spp. and against *Moniezia* spp. of tapeworm.

4.3 Contraindications

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

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.

Resistance to benzimidazoles has been reported in gastro-intestinal nematodes in horses. Therefore, the use of this product should be based on local epidemiological information about susceptibility of the nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

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 at any stage of pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only.
The suspension should be shaken well before use and is ready for use without further dilution.
The product can be administered by any standard dosing gun or drenching equipment. To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Routine dosage for cattle and horses:
7.5 mg fenbendazole/kg bodyweight as a single dose corresponding to 7.5 ml per 100 kg bodyweight.

Examples:

Body weight	Volume
Up to 100 kg	7.5 ml
100-200 kg	15 ml
200-300 kg	22.5 ml
300-400 kg	30 ml

For bodyweight in excess of 400 kg use 30 ml plus an additional 3.75 ml per 50 kg.

Treatment should be repeated every 6-8 weeks during the grazing season.
Treatment of specific indications in horses:
For the treatment of mucosal stages of *Trichonema* spp. - 30 mg/kg.
For the treatment of migrating stages of *Strongylus vulgaris* and *Strongylus edentatus* - 60 mg/kg.
Alternatively for the control of migrating larval stages of large strongyles and encysted mucosal stages of small strongyles (cyathostomes) administer 7.5 mg/kg fenbendazole daily for five days.
Diarrhoea caused by *Strongyloides westeri* in sucking foals should be treated with a dose of 25 ml Panacur 10% per 50 kg bodyweight (50 mg fenbendazole/kg bodyweight).

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

None known.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 14 days
Milk: 4 days
Horses:
Meat and offal: 14 days
Not authorised for mares producing milk for human consumption.

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 fenbendazole 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.
Fenbendazole 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 as well in the urine and milk. Fenbendazole is metabolised to its sulfoxide, then to sulfone and amines.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal Silicon Dioxide
Sodium Carboxymethyl Cellulose
Povidone 25000
Sodium Citrate Dihydrate
Citric Acid Monohydrate
Sodium Methyl Parahydroxybenzoate

Sodium Propyl Parahydroxybenzoate
Benzyl Alcohol
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.
Protect from freezing.

6.5 Nature and composition of immediate packaging

Multidose aluminium foil sealed polyethylene containers with polypropylene screw caps containing 250 ml, 1 litre and 2.5 litres of suspension. Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/111/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01/10/1999
Date of last renewal: 30/09/2009

10 DATE OF REVISION OF THE TEXT

September 2017