1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 100 mg/ml oral suspension for cattle and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains
Active substance:
Fenbendazole 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	4.835 mg
Sodium methyl parahydroxybenzoate	2.000 mg
Sodium propyl parahydroxybenzoate	0.216 mg
Silica, colloidal anhydrous	
Povidone K25	
Carmellose sodium	
Sodium citrate dihydrate	
Citric acid monohydrate	
Purified water	

White to off white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and horses.

3.2 Indications for use for each 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. The veterinary medicinal product 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, the veterinary medicinal product is effective against inhibited larvae of *Ostertagia* spp. and against *Moniezia* spp. of tapeworm.

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.
• 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.

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 and clothing consisting of 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 or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral use only.

The suspension should be shaken well before use and is ready for use without further dilution.
The veterinary medicinal product can be administered by any standard dosing gun or drenching equipment. To ensure a correct dosage, 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
101 - 200 kg	15 ml
201 - 300 kg	22.5 ml
301 - 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 of the veterinary medicinal product per 50 kg bodyweight (50 mg fenbendazole/kg bodyweight).

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

None 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

Cattle:
Meat and offal: 14 days.
Milk: 4 days.
Horses:
Meat and offal: 14 days.
Not authorised for use in mares 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 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.

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

Do not store above 25 °C.
Protect from frost.

5.4 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.

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)

VPA10996/111/001

8. DATE OF FIRST AUTHORISATION

01/10/1999

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

04/10/2024

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).