

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 10% oral suspension

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	2.00 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, sheep, horses and other equines.

3.2 Indications for use for each target species

Cattle and sheep

A broad spectrum anthelmintic for the treatment of sheep and cattle infected with mature and developing immature forms of nematodes of the gastrointestinal and respiratory tracts.

Cattle: For the treatment of cattle infected with:

Ostertagia spp.	Cooperia spp.
Trichostrongylus spp.	Nematodirus spp.
Haemonchus spp.	Oesophagostomum spp.
Bunostomum spp.	Strongyloides spp.
Trichuris spp.	Dictyocaulus viviparus

The product is usually effective against inhibited larvae of *Ostertagia* spp. and against *Moniezia* spp. of tapeworm.

Sheep: For the treatment of sheep infected with benzimidazole susceptible:

Ostertagia spp.	Haemonchus spp.
Trichostrongylus spp.	Nematodirus spp.
Cooperia spp.	Oesophagostomum spp.
Chabertia spp.	Bunostomum spp.
Strongyloides spp.	Dictyocaulus filaria

The product is usually effective against *Moniezia* spp. of tapeworm and may have useful but variable efficacy against *Trichuris* spp.

Horses

For the treatment and control of adult and immature round worms of the gastrointestinal tract in horses and other equines.

The product 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).

The product is also effective for the treatment and control of encysted mucosal 3rd and 4th stage small strongyle larvae and is also effective against encysted inhibited 3rd stage small strongyle larvae in the mucosa.

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

Fenbendazole also has an ovicidal effect on nematode eggs.

3.3 Contraindications

Do not use in horses and other equines intended for human consumption.

Fenbendazole as a medicated liquid feed should not be used in the treatment of clinical infestations in cattle and sheep.

3.4 Special warnings

When administered by divided dosage in the form of liquid feed, the product may not be effective against *Strongyloides* and *Trichuris* spp. in cattle and *Strongyloides*, *Dictyocaulus* and *Bunostomum* spp. in sheep.

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 bodyweight, 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 benzimidazoles (which include fenbendazole) has been reported in *Teladorsagia*, *Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants in a number of countries, including the EU. 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

When incorporating this product into liquid feed, after thoroughly shaking the suspension, measure the required volume of the suspension and add it to approximately 10% of the liquid feed. Thoroughly mix this material and then add the remaining liquid feed and once again mix to produce a homogenous dispersion.

Mix the medicated feed thoroughly prior to administration for example by rolling the drum or barrel.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not smoke, eat or drink when handling the veterinary medicinal product.

Avoid contact with the skin, eyes and mucous membranes. In case of accidental spillage onto the skin, eyes or mucous membranes, wash skin thoroughly with soap and water and rinse eyes and mucous membranes with plenty of water.

Personal protective equipment including impermeable rubber gloves should be worn when handling the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands thoroughly with soap and water after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, sheep, horses and other equines:
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 its local representative 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:

Can be used during pregnancy. Pregnant mares and young foals may also be safely treated with fenbendazole at the therapeutic dosage levels.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Shake container before use.

No dietary control is required before or after treatment.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, bodyweight should be determined as accurately as possible. Accuracy of the dosing device should be thoroughly checked.

Cattle and Horses: Administer orally 1 ml of the product per 13 kg bodyweight. (7.5 mg fenbendazole/kg bodyweight)

Practical dosage recommendations:

65 kg	5 ml
135 kg	10 ml
200 kg	15 ml
265 kg	20 ml
335 kg	25 ml
400 kg	30 ml

Above 400 kg, an extra 3.75 ml are required for each additional 50 kg bodyweight.

Sheep: Administer orally 0.5 ml per 10 kg bodyweight (5 mg fenbendazole/kg bodyweight)

Practical dosage recommendations:

Up to 10 kg	0.5 ml
11 to 20 kg	1.0 ml
21 to 30 kg	1.5 ml
31 to 40 kg	2.0 ml
41 to 50 kg	2.5 ml
51 to 60 kg	3.0 ml
61 to 70 kg	3.5 ml
71 to 80 kg	4.0 ml

Above 80 kg, an extra 0.5 ml is required for each additional 10 kg bodyweight.

For administration to cattle and sheep a standard dosing gun or drenching equipment can be used.

For administration to horses, thoroughly mix the product with grain or concentrate feed and give the full dosage as one administration.

Treatment should be repeated when natural re-infection of animals with parasitic worms occurs.

Horses:

Recommended dosage programme:

Inappropriate use of anthelmintics may increase resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on professional advice and take into account current best practice recommendations for parasite control.

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 5 ml of the product per 64 kg bodyweight daily for 5 days (7.5 mg fenbendazole/kg bodyweight daily for 5 days).

Single dose treatment:

For the treatment and control of encysted mucosal stages of small strongyles administer 3 ml of the product per 10 kg bodyweight (30 mg fenbendazole/kg bodyweight).

For the treatment and control of migrating and tissue stages of large strongyles administer 6 ml of the product per 10 kg bodyweight (60 mg fenbendazole/kg bodyweight).

For the treatment of diarrhoea caused by Strongyloides westeri in two to three week old sucking foals administer 5 ml of the product per 10 kg bodyweight (50 mg fenbendazole/kg bodyweight).

Do not mix with other products.

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

Benzimidazoles have a high margin of safety. No specific overdose symptoms are known. No specific action is required.

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: 12 days

Milk: 5 days

Sheep:

Meat and offal: 15 days

Milk: 7 days

Horses:

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13.

4.2 Pharmacodynamics

Fenbendazole is an anthelmintic belonging to the benzimidazole carbamates group. It acts by interfering with 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 gastrointestinal and respiratory nematodes.

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 in cattle is 10-18 hours and in sheep 21-33 hours. Fenbendazole and its metabolites are distributed throughout the body and high concentrations can be found in the liver.

The elimination of fenbendazole and its metabolites occurs primarily via the faeces (>90%) and to a small extent 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.

Liquid feed containing the product will remain stable for up to 3 months.

5.3 Special precautions for storage

Do not store above 25 °C.

Do not freeze.

Protect from frost.

5.4 Nature and composition of immediate packaging

1, 2, 5 or 10 litre multidose containers.

Container: opaque white, high density polyethylene flat-bottle.

Closure: Tamper proof aluminium foil seal with polypropylene screw cap.

1 or 2.5 litre multidose containers.

Container: opaque white, high density polyethylene flexi-bottle with polypropylene screw cap.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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 International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4076

8. DATE OF FIRST AUTHORISATION

24 January 1994

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

July 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 25 July 2025