SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 10% Oral suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	%w/v
Fenbendazole	10.00
Other substances	
Sodium methyl hydroxybenzoate	0.200
Sodium propyl hydroxybenzoate	0.0216
Benzyl alcohol	0.4835

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Clear colourless or virtually colourless oral suspension

4 CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep, horses and other equines

4.2 Indications for use, specifying the 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 gastro-intestinal 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 mayhave 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 andtissue 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.

4.3 Contra-indications

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 ofclinical infestations in cattle and sheep.

4.4 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 ineffectivetherapy:

- 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 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. 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.

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.

4.5 Special precautions for use

(i) Special precautions for use in animals

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.

Assess body weight as accurately as possible before calculating the dosage.

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

(ii) Special precautions to be taken by the person administering the medicinalproduct to the 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

4.7 Use during pregnancy, lactation or lay

The product can be administered to pregnant animals. Pregnant mares and young foals may also be safely treated with fenbendazole at the therapeutic dosage levels.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Shake container before use. For oral administration only.

No dietary control is required before or after treatment.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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

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 body weight.

Sheep: Administer orally 0.5 ml per 10 kg body weight(= 5 mg fenbendazole/kg body weight)

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 body weight.

The product is best administered to cattle with the Panacur 20ml Automatic Drencher and to sheep with the 5ml Sheep Drencher, but other standard dosingguns or drenching equipment may also 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

All horses should be routinely wormed with the single dose regimen every 6-8 weeks.

Treatment of encysted inhibited and encysted mucosal dwelling larvae should be performed in the autumn (ideally late October/November) and again in the Spring (ideally in February). However, for horses who fail to maintain condition or bought-in horses with unknown worming history, the treatment can be given at any time of the year.

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 body weight daily for 5 days (= 7.5 mg fenbendazole/kg body weight 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 body weight (= 30 mg fenbendazole / kg body weight).

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

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

Do not mix with other products.

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

Benzimidazoles have a high margin of safety. No specific overdose symptomsare known. No specific actions required.

4.11 Withdrawal periods

Cattle – Meat: 12 Days
Milk : 5 Days
Sheep - Meat: 15 Days
Milk : 7 Days

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 consumptionunder national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 gastro- intestinal and respiratory nematodes.

ATC Vet Code: QP52AC13

5.2 Pharmacokinetic particulars

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 anditsmetabolites 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl hydroxybenzoate
Sodium propyl hydroxybenzoate
Benzyl alcohol
Silica colloidal
Carmellose sodium
Povidone
Sodium citrate dihydrate
Citric Acid
Water purified

6.2 Incompatibilities

None

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening of the immediate packaging:

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

6.4 Special precautions for storage

Do not store above 25°C. Protect from frost. Do not freeze. Shake container before use. Keep the flat-bottle in its outer carton.

6.5 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 litre 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.

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

Any unused product or waste material should be disposed of in accordance with national requirements. DANGEROUS to aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

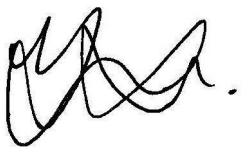
Vm 01708/4435

9. DATE OF FIRST AUTHORISATION

24 January 1994

10. DATE OF REVISION OF TEXT

July 2022



Approved: 29 July 2022