SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Small Animal 10% Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	% w/v
Fenbendazole	10.000
Other substances	
Sodium methyl hydroxybenzoate	0.200
Sodium propyl hydroxybenzoate	0.020
Benzyl alcohol	0.4835

3. PHARMACEUTICAL FORM

A white oral suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Domestic dogs, cats, puppies and kittens.

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for the treatment of domestic dogs and cats infected with immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts.

Adult dogs and cats: For the treatment of adult dogs and cats infected with gastro-intestinal nematodes and cestodes:
Ascarid spp*. (Toxocara canis, Toxocara cati , Toxascaris leonina)*
Ancylostoma spp.
Trichuris spp.
Uncinaria spp.
Taenia spp.

Puppies and kittens: For the treatment of puppies and kittens infected with gastro-intestinal nematodes and puppies infected with protozoa (*Giardia spp.)*.

Pregnant dogs: For the treatment of pregnant dogs to reduce prenatal infections with *Toxocara canis* and the transfer of *T.canis* and *Ancylostoma caninum* to their pups via the milk.

Also for the treatment of domestic dogs infected with lungworm *Oslerus (Filaroides) osleri* or protozoa Giardia spp*.,* and cats infected with lungworm *Aelurostrongylus abstrusus.*

Also has an ovicidal effect on nematode eggs.

4.3 Contra-indications

None known

4.4 Special warning for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
Assess body weight as accurately as possible before calculating the dosage.

Special precautions to be taken by the person administering the medicinal product to the animals
Direct contact with the skin should be kept to a minimum.
Wear impermeable rubber gloves and wash hands after use.

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.

4.6 Adverse reactions (frequency and seriousness)

Gastrointestinal signs (such as vomiting and diarrhoea) can occur in very rare cases in the dogs and cats.

The frequency of adverse reaction is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The product can be used in pregnant bitches.
As teratogenic effects in dogs and cats
cannot be completely ruled out in very rare cases, the treatment in the first two trimesters of pregnancy should be based on the benefit-risk evaluation by the responsible veterinary surgeon.

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.

Routine treatment of adult dogs and cats

1 ml per 1 kg body weight as a single oral dose.
(= 100 mg fenbendazole/kg body weight)

Practical dosage recommendations:

2 to 4 kg	4 ml
4 to 8 kg	8 ml
8 to 16 kg	16 ml
16 to 24 kg	24 ml
24 to 32 kg	32 ml
32 to 64 kg	64 ml

For dogs weighing over 64 kg, an extra 10 ml are required for each additional 10 kg body weight.

The dose should be added to feed, directly before feeding or administered by mouth directly after feeding.

Treatment should be repeated when natural re-infection with parasitic worms occurs. Routine treatment of adult animals with minimal exposure to infection is advisable 2 to 4 times per year. More frequent treatment at 6 to 8 weekly intervals is advisable for dogs in kennels.

Puppies and kittens under 6 months of age

0.5 ml per kg body weight daily for 3 consecutive days given by mouth directly after feeding to unweaned animals or added to feed for weaned animals, directly before feeding.
(= 50 mg fenbendazole/kg body weight daily for 3 days)

Practical dosage recommendations:

Up to 1 kg	0.5 ml daily for 3 days
1 to 2 kg	1 ml daily for 3 days
2 to 4 kg	2 ml daily for 3 days
4 to 6 kg	3 ml daily for 3 days
6 to 8 kg	4 ml daily for 3 days
8 to 10 kg	5 ml daily for 3 days

For puppies weighing over 10 kg, an extra 0.5 ml is required daily for each additional kg body weight.

Puppies should be treated at 2 weeks of age, 5 weeks of age and again before leaving the breeder's premises. Treatment may also be required at 8 and 12 weeks of age. Thereafter, frequency of treatment can be reduced unless the pups remain in kennels where reinfection occurs more readily.

Pregnant dogs

1 ml per 4 kg body weight daily from day 40 of pregnancy continuously to 2 days post-whelping (approximately 25 days) (= 25 mg fenbendazole/kg body weight daily)

Practical dosage recommendations:

4 kg	1 ml daily for approx. 25 days
8 kg	2 ml daily for approx. 25 days
12 kg	3 ml daily for approx. 25 days
20 kg	5 ml daily for approx. 25 days
40 kg	10 ml daily for approx. 25 days

For dogs weighing over 40 kg, an extra 1 ml is required daily for each additional 4 kg body weight.

As treatment of pregnant dogs is 98% effective, puppies from these dogs should themselves be treated with a 3 day course at 2 and 5 weeks of age.

Pregnant cats

Pregnant cats can be safely treated but only require a single treatment at the routine adult dose rate. Administer 1ml per kg body weight as a single dose.
(= 100mg fenbendazole/kg body weight)

Increased dosing for specific infections

For the treatment of clinical worm infestations in adult dogs and cats or *Giardia spp.* infections in dogs, administer 1 ml per 2 kg body weight daily for 3 consecutive days.
(= 50 mg fenbendazole/kg body weight daily for 3 days)

For the control of lungworm *Oslerus (Filaroides) osleri* in dogs administer
1 ml per 2 kg body weight for 7 consecutive days.
(= 50 mg fenbendazole/kg body weight daily for 7 days)
A repeat course of treatment may be required in some cases.

For the control of lungworm *Aelurostrongylus abstrusus* in cats administer
1 ml per 2 kg body weight for 3 consecutive days.
(= 50 mg fenbendazole/kg body weight daily for 3 days)

4.10 Overdose

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

4.11 Withdrawal(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fenbendazole is an anthelmintic belonging to the benzimidazole carbamates group. It acts by interfering in 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.
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5.2 Pharmacokinetic particulars

Fenbendazole is only partly absorbed after oral administration and is then metabolised in the liver. 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 sulphoxide, then to sulphone 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 dehydrate
Citric Acid
Water purified

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 x 100 ml multidose bottle.

Container: Opaque or solid white high density polyethylene bottle.

Closure: Foil seal with a polyethylene or polypropylene screw cap.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4077

9. DATE OF FIRST AUTHORISATION

29 January 1993

10. DATE OF REVISION OF TEXT

December 2024

Gavin Hall
Approved: 22 December 2024