SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 187.5 mg/g Oral Paste for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of oral paste contains:

Active substance:	
Fenbendazole	187.5 mg
Excipients:	
Methyl hydroxybenzoate (E218)	1.7 mg
Propyl hydroxybenzoate	0.16 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral paste.

White to light grey, smooth, spreadable, homogeneous paste.

4. CLINICAL PARTICULARS

4.1 Target species

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. The product also has an ovicidal effect on nematode eggs.

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* and *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).

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

4.3 Contraindications

None.

4.4 Special warning 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 or misadministration of the product'*

4.5 Special precautions for use

(i) Special precautions for use in animals
Assess bodyweight as accurately as possible before calculating the dosage.

(ii) 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 impermeable rubber gloves while administering the product
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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

The frequency of these adverse reactions after the use of this product is based on post marketing safety experience (pharmacovigilance).

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

4.7 Use during pregnancy, lactation or lay

Pregnant females may be safely treated with fenbendazole at therapeutic dosage levels. Owing to the reduced dose rate for treatment of pregnant dogs (25 mg fenbendazole/kg bodyweight daily) which cannot accurately be attained when using the syringe, it is recommended that alternative formulations of fenbendazole be used.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Should be administered orally by squeezing the paste from the syringe onto the back of the tongue after feeding.

Each injector contains 4.8 g paste, equivalent to 900 mg fenbendazole. To prepare the syringe for the first use, remove the syringe tip and turn the dial ring until the edge of the ring nearest the tip lines up with the zero (0) on the tube. Depress the plunger and discard any expelled paste. To protect householders, discard any unused paste into tissue and immediately dispose of via the household waste. The syringe is ready for use. The plunger has 18 graduations, each unit corresponding to 50 mg fenbendazole. Determine the number of graduations needed based on the body weight of the animal. Turn the ring on the plunger to the corresponding graduation.

Adult Cats and Dogs
Orally administer 2 syringe graduations per 1 kg bodyweight as a single dose (= 100 mg fenbendazole/kg bodyweight). Each syringe is sufficient to dose up to 9 kg bodyweight as a single dose.

Practical dosage recommendations:

Up to 1kg	*2 syringe graduations*
1.1 to 2 kg	4 syringe graduations
2.1 to 3 kg	6 syringe graduations
3.1 to 4 kg	8 syringe graduations
4.1 to 5 kg	10 syringe graduations
5.1 to 6 kg	12 syringe graduations
6.1 to 7 kg	14 syringe graduations
7.1 to 8 kg	16 syringe graduations
8.1 to 9 kg	18 syringe graduations

Additional syringes are required for dogs and cats weighing over 9 kg. For dogs and cats weighing over 9 kg, two extra syringe graduations are required for each additional 1 kg bodyweight as a single dose.

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 and cats in catteries or a breeders premises.

Puppies and kittens under 6 months of age
Only treat puppies and kittens weighing greater than 1 kg with this product. Orally administer the recommended dosages as described below, daily for 3 consecutive days

Each syringe is sufficient to dose up to 6 kg bodyweight for 3 consecutive days.

Practical dosage recommendations:

1.0 to 2 kg	2 syringe graduations daily for 3 days
2.1 to 3 kg	3 syringe graduations daily for 3 days
3.1 to 4 kg	4 syringe graduations daily for 3 days
4.1 to 5 kg	5 syringe graduations daily for 3 days
5.1 to 6 kg	6 syringe graduations daily for 3 days

Additional syringes are required if puppies weigh over 6 kg under 6 months old. For puppies weighing over 6 kg, an extra syringe graduation is required daily for each additional 1 kg bodyweight.

Puppies and kittens 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 puppies and kittens remain in kennels or kittens remain in catteries /breeders premises where reinfection occurs more readily.

Pregnant dogs
Owing to the reduced dose rate for treatment of pregnant dogs (25 mg fenbendazole/kg bodyweight daily) which cannot accurately be attained when using the syringe, it is recommended that alternative formulations of fenbendazole be used.

Pregnant cats
Pregnant cats can be safely treated with the product but only require a single treatment at the routine adult dose rate. Orally administer 2 syringe graduations per 1 kg bodyweight as a single dose (= 100 mg fenbendazole/kg bodyweight). Each syringe is sufficient to dose up to 9 kg bodyweight as a single dose.

INCREASED DOSING FOR SPECIFIC INFECTIONS

For the treatment of clinical worm infestations in adult dogs and cats or *Giardia* spp. infections in dogs and puppies, orally administer 1 syringe graduation per 1 kg bodyweight daily for 3 consecutive days (= 50 mg fenbendazole/kg bodyweight daily for 3 days).

For the control of lungworm *Oslerus (Filaroides) osleri* in dogs administer 1 syringe graduation per 1 kg bodyweight for 7 consecutive days (= 50 mg fenbendazole/kg bodyweight 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 syringe graduation per 1 kg bodyweight for 3 consecutive days (= 50 mg fenbendazole/kg bodyweight daily for 3 days).

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

Benzimidazoles have a high margin of safety.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazoles and related substances
ATC vet code: QP52AC13

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.

Fenbendazole is metabolised to its sulphoxide, then to sulphone and amines.

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 smaller extent in the urine and milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl hydroxybenzoate
Methyl hydroxybenzoate (E218)
Carbomer
Propylene glycol
Glycerol
Sorbitol
Sodium hydroxide
Water, purified

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

White opaque, graduated syringe made of high density polyethylene, containing 4.8 g paste. The adjustable injector is sealed with a high density polyethylene cap.

Pack sizes: cardboard box with 1 syringe or 10 syringes.

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, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4079

9. DATE OF FIRST AUTHORISATION

15 April 1998

10. DATE OF REVISION OF THE TEXT

June 2024

Approved 28 June 2024
Gavin Hall