# **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:**

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E218)	1.7 mg
Propyl parahydroxybenzoate	0.16 mg
Carbomer 980	
Propylene glycol mono propylene glycol	
Glycerol 85%	
Sorbitol, liquid (crystallising)	
Sodium hydroxide	
Water, purified	

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

#### 3. CLINICAL INFORMATION

# 3.1 Target species

Dogs, cats, puppies and kittens.

# 3.2 Indications for use for each target species

A broad spectrum anthelmintic for the treatment of domestic dogs and cats infected with immature and mature stages of nematodes of the gastrointestinal and respiratory tracts. The product also has an ovicidal effect on nematode eggs.

<u>Adult dogs and cats</u>: For the treatment of adult dogs and cats infected with gastrointestinal nematodes and cestodes:

Ascarid spp. (Toxocara canis, Toxocara cati and Toxascaris leonina) Ancylostoma spp.

Trichuris spp.

Uncinaria spp.

Taenia spp.

<u>Puppies and kittens</u>: For the treatment of puppies and kittens infected with gastrointestinal nematodes and puppies infected with protozoa (*Giardia* spp.).

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

#### 3.3 Contraindications

None.

# 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 bodyweight or misadministration of the product.

# 3.5 Special precautions for use

Special precautions for safe use in the target species:

Assess bodyweight as accurately as possible before calculating the dosage.

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 consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.

Wash hands after use.

<u>Special precautions for the protection of the environment:</u> Not applicable.

#### 3.6 Adverse events

Dogs, cats, puppies and kittens:

Very rare	Gastrointestinal disorders (e.g. vomiting <sup>1</sup>
(<1 animal / 10,000 animals treated,	and diarrhoea <sup>1</sup> ).
including isolated reports):	

<sup>&</sup>lt;sup>1</sup> mild

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:

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.

# 3.8 Interaction with other medicinal products and other forms of interaction

None known.

#### 3.9 Administration routes and dosage

Oral use.

The veterinary medicinal product 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 bodyweight 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 reinfection 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 breeder's 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 /breeder's 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.

# <u>Increased dosing for specific infections:</u>

For the treatment of <u>clinical</u> 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).

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

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

Benzimidazoles have a high margin of safety.

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

Not applicable.

#### 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 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 gastrointestinal and respiratory nematodes.

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

#### 4.3 Pharmacokinetics

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.

### **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: 2 years.

# 5.3 Special precautions for storage

Do not store above 25 °C.

### 5.4 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.

# 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 06376/4079

# 8. DATE OF FIRST AUTHORISATION

15 April 1998

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

September 2025

#### 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

Find more product information by searching for the 'Product Information Database' on <a href="https://www.gov.uk">www.gov.uk</a>.

Gavin Hall

Approved: 06 November 2025