SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Granules 222 mg/g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Fenbendazole 222.22 mg/g

Excipients:
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Granules.
White or yellowish-white granular powder.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats, puppies and kittens.

4.2 Indications for use, specifying the target species

Dogs and cats
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 weaned 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 dogs infected with lungworm *Oslerus (Filaroides) osleri* or protozoa *Giardia* spp. and cats infected with lungworm *Aelurostrongyles abstrusus*

Panacur also has an ovicidal effect on nematode eggs.

4.3 Contraindications

None.

4.4 Special warning for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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.
Avoid inhalation of granule dust. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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

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

Pregnancy:
Can be used during pregnancy in dogs and cats.

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 veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Oral use.

Routine treatment of adult dogs and cats:
Administer 100 mg fenbendazole per 1 kg (2.2 lb) bodyweight as a single dose.

Practical dosage recommendations:
1 g sachet /dose treats **2** kg (4.4 lb) bodyweight as a single dose (1.1 – 2.2 kg)
1.8 g sachet / dose treats **4** kg (8.8 lb) bodyweight as a single dose (2.2 – 4.4kg)
4.5 g sachet /dose treats **10** kg (22 lb) bodyweight as a single dose (5 – 10 kg)

For dogs weighing over 10 kg (22 lb), additional sachets are required according to the additional bodyweight.

Assess bodyweight as accurately as possible and then administer one or a combination of the above sachets, which most closely doses this bodyweight. The dose should be administered by mixing into the feed.

e.g. For a 9 kg dog = **2** kg dose (1 g sachet) + **4** kg dose (1.8 g sachet) + **4** kg dose (1.8 g sachet).

i.e. one x 1 gram sachet + two x 1.8 gram sachets. (**10** kg dose)
or, one x 4.5 gram sachet (**10** kg 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.

Weaned puppies and kittens under six months of age:
Administer 50 mg fenbendazole per 1 kg (2.2 lb) bodyweight daily for 3 consecutive days.

Practical dosage recommendations:
1 g sachet/dose treats **4** kg (8.8 lb) bodyweight (minimum weight 2.2 kg) dosed daily for three consecutive days (2.2 – 4.4 kg).
1.8 g sachet/dose treats **8** kg (17.6 lb) bodyweight dosed daily for three consecutive days (4.5– 8kg).
4.5 g sachet/dose treats **20** kg (44 lb) bodyweight dosed daily for three consecutive days (10– 20 kg).

For dogs/puppies weighing over 20 kg (44 lb), additional sachets are required according to the additional bodyweight.

Assess bodyweight as accurately as possible and then administer one or a combination of the above sachets, which most closely doses this bodyweight. The dose should be administered by mixing into the feed.

e.g. For a 9 kg puppy = **4** kg dose (1 gram sachet) + **8** kg dose (1.8 gram sachet) daily for 3 consecutive days.

i.e. one x 1 gram sachet + one x 1.8 gram sachet (**12** kg dose) daily for 3 days or three x 1 gram sachet (**12** kg dose) daily for 3 days.

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 re-infestation occurs more readily.

Pregnant dogs:
Administer 25 mg fenbendazole per 1 kg (2.2 lb) bodyweight daily from day 40 of pregnancy continuously to 2 days post-whelping (approximately 25 days).

Practical dosage recommendations:
1 g sachet/dose treats **8** kg (17.6 lb) bodyweight daily approx. 25 days.
1.8 g sachet/dose treats **16** kg (35.2 lb) bodyweight daily approx. 25 days.
4.5 g sachet/dose treats **40** kg (88 lb) bodyweight daily approx. 25 days.

For bitches weighing over 40 kg, additional sachets are required according to the additional bodyweight.

Increased dosing for specific infections:
For the treatment of clinical worm infestations in adult dogs and cats or *Giardia spp.* infections in dogs, administer 50 mg fenbendazole per 1 kg (2.2 lb) bodyweight daily for 3 consecutive days.

For the control of lungworm *Oslerus (Filaroides) osleri* in dogs administer 50 mg fenbendazole per 1 kg (2.2 lb) bodyweight, daily for 7 consecutive days. A repeat course of treatment may be required in some cases.

For the control of lungworm *Aelurostrongylus abstrusus* in cats administer 50mg fenbendazole per 1 kg (2.2 lb) bodyweight daily for 3 consecutive days.

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

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazoles and related substances
ATCvet 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.

5.2 Pharmacokinetic particulars

Fenbendazole is only partly absorbed from the intestine and reaches maximum plasma concentration in dogs 6 - 24 hours after oral administration. In cats the mean maximum serum concentration of fenbendazole was reached about 4 hours after treatment. Administration of fenbendazole in food did significantly increase its bioavailability compared to the administration on an empty stomach.
Fenbendazole is metabolised mainly by enzymes of the cytochrome P-450 system in the liver. The major oxidative metabolite is fenbendazole sulfoxide which is further metabolised to fenbendazole sulfone.

Fenbendazole and its metabolites are distributed throughout the body, but highest concentrations are found in the liver.
The elimination half-life from plasma is about 15 hours after oral administration.

Fenbendazole and its metabolites are predominantly excreted via the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone 2500
Maize starch

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Low density polyethylene/aluminium foil/paper laminated sachet.

Pack sizes: 1 g, 1.8 g and 4.5 g sachets.

Cardboard boxes containing:

1 g x 100
1.8 g x 3
1.8 g x 3 x 10
1.8 g x 90
4.5 g x 3
4.5 g x 3 x 10
4.5 g x 60

Not all pack sizes may be marketed.

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

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 06376/4075

9. DATE OF FIRST AUTHORISATION

23 January 1998

10. DATE OF REVISION OF THE TEXT

June 2024

Approved 28 June 2024
Gavin Hall