

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur granules 22.2% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	%w/w
Fenbendazole	22.2

For 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

Domestic 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 Contra-indications

None

4.4 Special warning for each target species

None

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 medicinal product to the 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.

4.7 Use during pregnancy or lactation

The product can also be safely administered to pregnant 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

Routine treatment of adult dogs and cats

Administer 100mg fenbendazole per 1kg (2.2lb) bodyweight as a single dose.

Practical dosage recommendations:

1 g sachet /dose Treats **2kg** (4.4lb) bodyweight as a single dose (1.1 – 2.2kg)

1.8 g sachet / dose Treats **4kg** (8.8lb) bodyweight as a single dose (2.2 – 4.4kg)

4.5 g sachet /dose Treats **10kg** (22lb) bodyweight as a single dose (5 – 10kg)

For dogs weighing over 10kg (22lb), 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 9kg dog = **2kg** dose (1g sachet) + **4kg** dose (1.8g sachet) + **4kg** dose (1.8g sachet).

i.e. one x 1gram sachet + two x 1.8gm sachets. (**10kg** dose)
or, one x 4.5gram sachet (**10kg** 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 50mg fenbendazole per 1kg (2.2lb) bodyweight daily for 3 consecutive days.

Practical dosage recommendations:

1 g sachet /dose Treats **4kg** (8.8lb) bodyweight (minimum weight 2.2kg) dosed daily for three consecutive days (2.2 – 4.4kg)

1.8 g sachet / dose Treats **8kg** (17.6lb) bodyweight dosed daily for three consecutive days (4.5– 8kg)

4.5 g sachet /dose Treats **20kg** (44lb) bodyweight dosed daily for three consecutive days (10– 20kg)

For dogs/puppies weighing over 20kg (44lb), 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 9kg puppy = **4kg** dose (1gm sachet) + **8kg** dose (1.8gm sachet) daily for 3 consecutive days.

i.e. one x 1 gram sachet + one x 1.8 gram sachet (**12kg** dose) daily for 3 days
or, three x 1 gram sachet (**12kg** 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 25mg fenbendazole per 1kg (2.2lb) bodyweight daily from day 40 of pregnancy continuously to 2 days post-whelping (approximately 25 days).

Practical dosage recommendations:

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

For bitches weighing over 40kg, 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 50mg fenbendazole per 1kg (2.2lb) bodyweight daily for 3 consecutive days.

For the control of lungworm *Oslerus (Filaroides) osleri* in dogs administer 50mg fenbendazole per 1kg (2.2lb) 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 1kg (2.2lb) 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

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 gastrointestinal and respiratory nematodes.

ATC Vet Code: QP52AC13

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 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

No special precautions for storage.

6.5 Nature and composition of immediate packaging

Pack sizes: 1g, 1.8g and 4.5g sachets.
Container: Low density polyethylene/aluminium foil/paper laminated sachet.
Not all pack sizes may be marketed.

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

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 UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4427

9. DATE OF FIRST AUTHORISATION

23 January 1998

10. DATE OF REVISION OF TEXT

June 2016.

Approved: 08 June 2016

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.