

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10996/119/001**

Case No: 7004819

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Intervet Ireland Limited

Magna Drive, Magna Business Park, Dublin 24, Ireland

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Panacur Granules (Wormer for Cats, Dogs, Kittens, and Puppies)

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless revoked, shall continue in force from **11/08/2008** until **30/09/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Granules (Wormer for Cats, Dogs, Kittens and Puppies)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g contains :

Active Substance

Fenbendazole Ph. Eur. 0.22 g

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Granules.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

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 and 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 as an aid in the control of the protozoan *Giardia* in puppies

Pregnant bitches :

For the treatment of pregnant bitches to reduce prenatal infections of *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*, and as an aid in the control of the protozoan *Giardia*, and treatment of cats infected with lungworm *Aelurostrongylus abstrusus*.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be administered to animals at any stage of pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No interaction known.

4.9 Amounts to be administered and administration route

Routine treatment of adult dogs and cats :

Administer 100 mg fenbendazole per 1 kg (2.2 lbs) 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 (2.2-4.4 kg)
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 lbs), 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 g sachet + two x 1.8 g sachets (**10 kg** dose)
 or, one 4.5 g 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 lbs) bodyweight daily for 3 consecutive days.

Practical dosage recommendations :

1 g sachet/dose (2.2 – 4.4 kg)	Treats 4 kg (8.8 lb) bodyweight (minimum weight 2.2 kg) dosed daily for three consecutive days
1.8 g sachet/dose	Treats 8 kg (17.6 lb) bodyweight dosed daily for three consecutive days (4.5 – 8 kg)
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 lbs), 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 g sachet) + **8 kg** dose (1.8 g sachet) daily for three consecutive days
 i.e.: one x 1 g sachet + one x 1.8 g sachets (**12 kg** dose) daily for 3 days
 or, three x 1 g 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 weeks and 12 weeks of age. Thereafter, frequency of treatment can be reduced unless the pups remain in kennels where reinfestation occurs more readily.

Pregnant bitches :

Administer 25 mg fenbendazole per 1 kg (2.2 lbs) 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 approximately 25 days
1.8 g sachet/dose	Treats 16 kg (35.2 lb) bodyweight daily approximately 25 days
4.5 g sachet/dose	Treats 40 kg (88 lb) bodyweight daily approximately 25 days.

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For pregnant bitches weighing over 40 kg, additional sachets are required according to the additional bodyweight. As this treatment of pregnant bitches is 98% effective, puppies from these bitches should themselves be treated with a 3 day course at 2 and 5 weeks of age with Panacur Wormer.

Increased dosing for specific infections :

For the treatment of clinical worm infestations in adult dogs and cats or as an aid in the control of *Giardia spp.* infections in dogs, administer 50 mg fenbendazole per 1 kg (2.2 lbs) 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 lbs) 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 50 mg fenbendazole per 1 kg (2.2 lbs) bodyweight daily for 3 consecutive days

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

No specific overdose reactions known.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Febendazole is an antihelminthic belonging to the benzimidazole-carbamate group. It acts by interfering with the energy metabolism of the nematode.

The antihelminthic affects both adult and immature states of the gastro-intestinal and respiratory nematodes. This antihelminthic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli.

5.2 Pharmacokinetic properties

Febendazole is only partly absorbed after oral administration and is then metabolised in the liver. Febendazole and its metabolites are distributed throughout the body but the highest concentrations are found in the liver. The elimination of febendazole and its metabolites occurs primarily via the faeces (>90%) and to a smaller extent in the urine and milk.

Febendazole is metabolised to its sulfoxide, and then to sulfone and amines.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch Ph. Eur.

Lactose Monohydrate Ph. Eur.

Povidone 25000 Ph. Eur.

6.2 Incompatibilities

None known.

6.3 Shelf-life

5 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Container:	Low density polyethylene/aluminium foil/paper laminated sachet
Pack sizes:	1g, 1.8g and 4.5g sachets
Package quantities:	3 x 1.0g, 100 x 1.0g, 3 x 1.8g, 90 x 1.8g, 3 x 4.5g, 60 x 4.5g.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10996/119/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004

10 DATE OF REVISION OF THE TEXT

11th August 2008