1 NAME OF THE VETERINARY MEDICINAL PRODUCT FOLLOWED BY THE STRENGTH AND THE PHARMACEUTICAL FORM

Panacur 18.75% Oral Paste

2 NAME AND PROPORTION OF EACH ACTIVE SUBSTANCE, AND OF ANY EXCIPIENT, IF KNOWLEDGE OF THE EXCIPIENT IS NEEDED FOR SAFETY REASONS

Active substance:	%w/w
Fenbendazole	18.75
Other substances:	
Methyl hydroxybenzoate	0.17
Propyl hydroxybenzoate	0.016

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral paste

4 CLINICAL PARTICULARS

4.1 Target species

Domestic 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. Panacur 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 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.
Wear impermeable rubber gloves while administering the product
Wash hands after use.

4.6 **Adverse reactions (frequency and seriousness)**

None known

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 can not accurately be attained when using the Panacur Paste 5 g 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**

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

Adult Cats and Dogs

Orally administer 2 syringe graduations per 1 kg bodyweight as a single dose (= 100 mg fenbendazole/kg bodyweight). Each 5 g 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
Orally administer 1 syringe graduation per 1 kg bodyweight daily for 3 consecutive days (= 50 mg fenbendazole/kg bodyweight daily for 3 consecutive days). Each 5 g syringe is sufficient to dose up to 6 kg bodyweight for 3 consecutive days.

Practical dosage recommendations:

Up to 1 kg	1 syringe graduation daily for 3 days
1.1 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 for puppies under 6 months, weighing over 6 kg. 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 can not accurately be attained when using the Panacur Paste 5 g syringe, it is recommended that alternative formulations of fenbendazole be used.

Pregnant cats
Pregnant cats can be safely treated with Panacur Paste 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 5 g 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 periods for the various foodstuffs, including those for which the withdrawal period is zero**

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 gastro-intestinal and respiratory nematodes.

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

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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 hydroxy benzoate
Methyl hydroxybenzoate
Carbomer
Propylene Glycol
Glycerol
Sorbitol
Sodium Hydroxide
Purified water

6.2 Major incompatibilities

None

6.3 Shelf life, when necessary after reconstitution of the medicinal products or when the immediate packaging is opened for the first time

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

White syringe impervious to light made of high density polyethylene, containing 5g paste. The adjustable injector is sealed with a high density polyethylene cap.

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

7. MARKETING AUTHORISATION HOLDER

Intervet UK Ltd.
Walton
Milton Keynes, Bucks.
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4448

9. **DATE OF FIRST AUTHORISATION OR DATE OF RENEWAL OF THE AUTHORISATION**

14 April 2003

10. **DATE OF REVISION OF TEXT**

June 2006

11. **ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE**