SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Small Animal 2.5% oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	% w/v
Fenbendazole	2.500
Other substances	
Sodium methyl hydroxybenzoate	0.200
Sodium propyl hydroxybenzoate	0.0216
Benzyl alcohol	0.4835

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

A white, practically odourless, oral suspension

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.

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 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 domestic dogs infected with lungworm *Oslerus (Filaroides) osleri* or protozoa Giardia spp., and cats infected with lungworm *Aelurostrongylus abstrusus.*

Also has an ovicidal effect on nematode eggs.

4.3 Contra-indications

None known

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 and wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

The product can be safely administered to pregnant females.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Shake container before use.

Routine treatment of adult dogs and cats
4 ml per 1 kg bodyweight as a single oral dose.
(= 100 mg fenbendazole/kg bodyweight)

The dose should be added to feed, directly before feeding or administered by mouth directly after feeding.

Treatment should be repeated when natural re-infestation 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 and 8 weekly intervals is advisable for dogs in kennels.

Puppies and kittens under six months of age
2 ml per kg bodyweight daily for 3 consecutive days given by mouth directly after feeding to unweaned animals or added to feed for weaned animals, directly before feeding.
(= 50 mg fenbendazole/kg bodyweight daily for 3 days)

Practical dosage recommendations:

250 g	0.5 ml daily for 3 days
500 g	1 ml daily for 3 days
1 kg	2 ml daily for 3 days
1.5 kg	3 ml daily for 3 days
2 kg	4 ml daily for 3 days

For puppies weighing over 2 kg, an extra 2 ml is required daily for each additional kg bodyweight.

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 reinfestation occurs more readily.

Pregnant dogs
1 ml per 1 kg bodyweight daily from day 40 of pregnancy continuously to 2 days post-whelping (approximately 25 days)
(= 25 mg fenbendazole/kg bodyweight daily)

Practical dosage recommendations:

2 to 4 kg	4 ml daily for approx. 25 days
4 to 8 kg	8 ml daily for approx. 25 days
8 to 16 kg	16 ml daily for approx. 25 days

As treatment of pregnant dogs is 98% effective, puppies from these dogs should themselves be treated with a 3 day course at 2 and 5 weeks of age.

Pregnant cats
Pregnant cats can be safely treated but only require a single treatment at the routine adult dose rate. Administer 4ml per kg bodyweight as a single dose.
(=100mg fenbendazole/kg 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 2 ml per 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 2 ml per kg bodyweight, daily 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 2 ml per kg bodyweight daily 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.
ATC Vet Code: QP52AC13

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 small extent in the urine and milk.
Fenbendazole is metabolised to its sulphoxide, then to sulphone and amines.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl hydroxybenzoate
Sodium propyl hydroxybenzoate
Benzyl alcohol
Silica colloidal
Carmellose sodium
Povidone
Sodium citrate dehydrate
Citric Acid
Water purified

6.2 Major incompatibilities

None

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

3 years

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and composition of immediate packaging

Multidose container of 100 ml. Container: Opaque white high density polyethylene. Closure: Foil seal with polyethylene screw cap.

6.6 Special precautions for disposal of unused veterinary medicinal products 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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4428

9. DATE OF FIRST AUTHORISATION

30 December 2002

10. DATE OF REVISION OF TEXT

April 2021

Approved: 01/04/21