SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur small animal 100 mg/ml oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Fenbendazole 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	4.835 mg
Sodium methyl parahydroxybenzoate	2.000 mg
Sodium propyl parahydroxybenzoate	0.216 mg
Silica, colloidal anhydrous	
Povidone K25	
Carmellose sodium	
Sodium citrate dihydrate	
Citric acid monohydrate	
Purified water	

White to off white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats, puppies and kittens.

3.2 Indications for use for each target species

A broad spectrum anthelmintic for the treatment of domestic dogs and cats infected with immature and mature stages of nematodes of the gastrointestinal and respiratory tracts.

Adult dogs and cats: For the treatment of adult dogs and cats infected with gastrointestinal 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 gastrointestinal 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.

3.3 Contraindications

None.

3.4 Special warnings

The use of the veterinary medicinal product should be based on local epidemiological information about susceptibility of the nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Assess body weight 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.

Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.

Wash hands thoroughly with soap and water after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs, cats, puppies and kittens:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal disorders (e.g. vomiting or diarrhoea).

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The product can be used in pregnant bitches.
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 veterinary surgeon.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Shake container before use.

Routine treatment of adult dogs and cats

1 ml per 1 kg body weight as a single oral dose.
(= 100 mg fenbendazole/kg body weight)

Practical dosage recommendations:

2 to 4 kg	4 ml
4 to 8 kg	8 ml
8 to 16 kg	16 ml
16 to 24 kg	24 ml
24 to 32 kg	32 ml
32 to 64 kg	64 ml

For dogs weighing over 64 kg, an extra 10 ml are required for each additional 10 kg body weight.

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

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.

Puppies and kittens under 6 months of age

0.5 ml per kg body weight 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 body weight daily for 3 days)

Practical dosage recommendations:

Up to 1 kg	0.5 ml daily for 3 days
1 to 2 kg	1 ml daily for 3 days
2 to 4 kg	2 ml daily for 3 days
4 to 6 kg	3 ml daily for 3 days
6 to 8 kg	4 ml daily for 3 days
8 to 10 kg	5 ml daily for 3 days

For puppies weighing over 10 kg, an extra 0.5 ml is required daily for each additional kg body weight.

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 reinfection occurs more readily.

Pregnant dogs

1 ml per 4 kg body weight daily from day 40 of pregnancy continuously to 2 days post-whelping (approximately 25 days) (= 25 mg fenbendazole/kg body weight daily).

Practical dosage recommendations:

4 kg	1 ml daily for approx. 25 days
8 kg	2 ml daily for approx. 25 days
12 kg	3 ml daily for approx. 25 days
20 kg	5 ml daily for approx. 25 days
40 kg	10 ml daily for approx. 25 days

For dogs weighing over 40 kg, an extra 1 ml is required daily for each additional 4 kg body weight.

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 1ml per kg body weight as a single dose.
(= 100mg fenbendazole/kg body weight)

Increased dosing for specific infections

For the treatment of clinical worm infestations in adult dogs and cats or *Giardia spp.* infections in dogs, administer 1 ml per 2 kg body weight daily for 3 consecutive days.
(= 50 mg fenbendazole/kg body weight daily for 3 days)

For the control of lungworm *Oslerus (Filaroides) osleri* in dogs administer
1 ml per 2 kg body weight for 7 consecutive days.
(= 50 mg fenbendazole/kg body weight 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 ml per 2 kg body weight for 3 consecutive days.
(= 50 mg fenbendazole/kg body weight daily for 3 days)

To ensure a correct dosage, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not freeze.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 x 100 ml multidose bottle.
Container: Opaque or solid white high density polyethylene bottle.
Closure: Foil seal with a polyethylene or polypropylene screw cap.

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

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.