ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur PetPaste 187.5 mg/g oral paste for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g oral paste contains:

Active substance:
Fenbendazole 187.5 mg

Excipients:
Methyl-4-hydroxybenzoate (E 218) 1.7 mg
Propyl-4-hydroxybenzoate (E 216) 0.16 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Paste

White to light grey, smooth, spreadable, homogenous paste.

4. CLINICAL PARTICULARS

4.1 Target species

Dog and cat

4.2 Indications for use, specifying the target species

For the treatment of infections with gastrointestinal nematodes in kittens and adult cats and in puppies and adult dogs. In dogs additionally as an aid in the control of the protozoan *Giardia.*

Kittens and adult cats:
Infection with the following gastrointestinal nematodes:
Toxocara cati (adult stages)
Ancylostoma tubaeforme (immature and adult stages)

Puppies and adult dogs:
Infection with the following gastrointestinal parasites:
Toxocara canis (adult stages)
Ancylostoma caninum (adult stages)
Uncinaria stenocephala (immature and adult stages) and
Giardia spp.

4.3 Contraindications

Do not use in pregnant bitches up to day 39.
Do not use in pregnant queens.
Refer to 4.7 'Use during pregnancy and lactation'.

4.4 Special warnings for each target species

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

4.5 Special precautions for use

Special precautions for use in animals

As accuracy of dosing is limited, the veterinary medicinal product should not be used in kittens and puppies weighing less than 1 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid direct contact with the skin as far as possible.
Wash hands after use.
People with known hypersensitivity to the active ingredient or any excipient should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Treated animals may occasionally develop vomiting or mild diarrhoea in connection with the deworming.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use in pregnant bitches up to day 39.
Panacur PetPaste can be used for the treatment of pregnant bitches during the last third of pregnancy. However, as teratogenic effects caused by the fenbendazole metabolite oxfendazole cannot be ruled out entirely in rare cases, use only according to the benefit/risk assessment by the responsible veterinarian.
Do not use in pregnant queens.

Lactation:
The product can be used in lactating bitches and queens.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Panacur PetPaste should be administered straight into the mouth after feeding by squeezing the paste from the injector onto the base of the tongue.
Alternatively, the paste can also be mixed into the food.

Each injector contains 4.8 g paste, equivalent to 900 mg fenbendazole. To prepare the Panacur PetPaste syringe for the first use, remove the syringe tip and turn the dial ring until the edge of the ring nearest the tip lines up with the zero (0) on the tube. Depress the plunger and discard any expelled paste. The syringe is ready for use. The plunger has 18 graduations, each unit corresponding to 50 mg fenbendazole. Determine the number of graduations needed based on the bodyweight of the animal. Turn the ring on the plunger to the corresponding graduation.

One Panacur PetPaste injector is suitable for use in pets with a bodyweight of up to 6 kg. If the body weight of an animal exceeds 6 kg, it is necessary to use more than one injector.

Adult cats
The dose is 75 mg fenbendazole/kg bodyweight (BW) per day on two successive days.

A daily dose for 2 kg body weight corresponds to 3 graduations on the plunger. The resulting dosage schedule is as follows:

up to 2 kg BW 3 graduations of the injector daily for 2 days
2.1 to 4 kg BW 6 graduations on the injector daily for 2 days
4.1 to 6 kg BW 9 graduations of the injector daily for 2 days
etc.

The bodyweight of an animal to be treated should be determined as accurately as possible for the purpose of calculating the required dose.

Kittens, puppies and adult dogs
The dose is 50 mg fenbendazole/kg BW per day on three successive days.

The dosage schedule is as follows:

1.0 to 2 kg BW 2 graduations on the injector daily for 3 days
2.1 to 3 kg BW 3 graduations of the injector daily for 3 days
3.1 to 4 kg BW 4 graduations on the injector daily for 3 days
4.1 to 5 kg BW 5 graduations of the injector daily for 3 days
5.1 to 6 kg BW 6 graduations of the injector daily for 3 days
etc.

Particularly under conditions of heavy challenge, the elimination of *Ancylostoma tubaeforme* in adult cats, of *Giardia* spp. in dogs and of ascarids especially in puppies and kittens, can be incomplete in individual animals so that a potential risk of infection to humans remains. A fecal examination should therefore be conducted and on the basis of the results a re-treatment given if necessary, according to the judgement of the veterinarian.

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

In dogs after treatment at three times the recommended dosage or for three times the proposed duration of use transient induction of lymphoid hyperplasia in the gastric mucosa may be seen. These findings do not have any clinical relevance.
In cats no treatment related adverse effects were observed after they were overdosed with the same dosage scheme.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazoles and related substances
ATC vet code: QP52AC13

5.1 Pharmacodynamic properties

Fenbendazole is an anthelmintic of the benzimidazole carbamate group which disrupts the energy metabolism of nematodes. The underlying mechanism of the anthelmintic action of fenbendazole is inhibition of the polymerisation of tubulin to microtubules. Fenbendazole is effective against adult and immature gastrointestinal nematodes.

The mode of action of benzimidazoles such as fenbendazole against Giardia spp. is also based on a disruption of the parasite's microtubular system. Treated Giardia lamblia trophozoites show fragmented ventral discs and deposits in the microtubular system while the flagellae appear to be unaffected.

5.2 Pharmacokinetic particulars

After oral administration fenbendazole is absorbed slowly and only partially. Following absorption from the digestive tract fenbendazole is metabolised in the liver to sulfoxide (oxfendazole) and further to sulfone and amine derivatives. Fenbendazole and its metabolites disperse slowly throughout the body, reaching high concentrations in the liver. Unchanged and metabolised fenbendazole is excreted primarily (> 90%) with the faeces, and to a small extent also via the urine and milk**.**

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Carbomer
Propylene glycol
Glycerol (85 per cent)
Sorbitol
Sodium hydroxide
Water, purified

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: 28 days

6.4. Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

White injector, impervious to light, made of high density polyethylene, containing 4.8 g paste, equivalent to 900 mg fenbendazole. The adjustable injector is sealed with a high density polyethylene cap.

Pack sizes: cardboard box with one injector or ten injectors.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.