[Version 9,03/2022] corr. 11/2022

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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E 218)	1.7 mg
Propyl parahydroxybenzoate	0.16 mg
Carbomer 980	
Propylene glycol	
Glycerol 85%	
Sorbitol, Liquid (Crystallizing)	
Sodium hydroxide	
Water, purified	

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each 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.

3.3 Contraindications

Do not use in pregnant bitches up to day 39.
Do not use in pregnant queens.
Refer to 3.7 'Use during pregnancy and lactation'.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting, diarrhoea[1]

[1] Usually mild.

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:
Do not use in pregnant bitches up to day 39.
The veterinary medicinal product 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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

The veterinary medicinal product 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 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 injector of the veterinary medicinal product 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. Underdosing could result in ineffective use and may favour resistance development.

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.

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

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.

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 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.

4.3 Pharmacokinetics

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**.**

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.
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

AT, CZ, DE, DK, ES, GR, HU, IE, PT: Veterinary medicinal product subject to prescription.
BE, LU, NL: Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box – outer box for 10 individual injectors

Cardboard Box of each individual injector

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur PetPaste 187.5 mg/g oral paste

2. STATEMENT OF ACTIVE SUBSTANCES

1g contains:
Fenbendazole 187.5 mg

3. PACKAGE SIZE

1 injector containing 4.8 g oral paste

10 injectors, each injector containing 4.8 g oral paste

4. TARGET SPECIES

Dogs and cats

5. INDICATIONS

For products not subject to veterinary prescription (BE, LU, NL):
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*.

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use by 28 days.
Once opened use by

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Injector

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur PetPaste

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Fenbendazole 187.5 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP: {month/year}

Once opened use by

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

1 g oral paste contains:

Active substance:	
Fenbendazole	187.5 mg
Excipients:	
Methyl parahydroxybenzoate (E 218)	1.7 mg
Propyl parahydroxybenzoate	0.16 mg

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

3. Target species

Dogs and cats.

4. Indications for use

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.

5. Contraindications

Do not use in pregnant bitches up to day 39.
Do not use in pregnant queens.
Refer also to Section 6. “Special warnings”.

6. Special warnings

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

Special precautions for safe use in the target species:
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.

Pregnancy:
Do not use in pregnant bitches up to day 39.
The veterinary medicinal product 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.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
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.

7. Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Vomiting, diarrhoea[1])

[1] Usually mild

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.

Each injector contains 4.8 g paste, equivalent to 900 mg fenbendazole. The plunger has 18 graduations, each unit corresponding to 50 mg fenbendazole. The desired number of units are selected by turning a ring on the plunger.

One injector of the veterinary medicinal product 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 bodyweight corresponds to 3 graduations on the plunger. The resulting dosage schedule is as follows:

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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:

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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.

Underdosing could result in ineffective use and may favour resistance development.

9. Advice on correct administration

To prepare the syringe of the veterinary medicinal product 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.

The veterinary medicinal product 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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

AT, CZ, DE, DK, ES, GR, HU, IE, PT: Veterinary medicinal product subject to prescription.
BE, LU, NL: Veterinary medicinal product not subject to prescription.

14. Marketing authorisation numbers and pack sizes

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

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Intervet Productions S.A.
Rue de Lyons
F-27460 Igoville
France

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.