

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton box/10 syringes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 187.5 mg/g Oral Paste for dogs and cats
Fenbendazole

2. STATEMENT OF ACTIVE SUBSTANCES

Fenbendazole 187.5 mg.

3. PHARMACEUTICAL FORM

Oral Paste.

4. PACKAGE SIZE

10 syringes, each containing 4.8 g oral paste.

5. TARGET SPECIES

Dogs, cats, puppies and kittens.

6. INDICATION(S)

Wormer for dogs, cats, puppies and kittens.

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 Oral Paste also has an ovicidal effect on nematode eggs.

For the treatment of adult dogs and cats infected with gastro-intestinal nematodes and cestodes, including *Ascarid* spp (*Toxocara canis*, *Toxocara cati* and *Toxascaris leonina*), *Ancylostoma* spp, *Trichuris* spp, *Uncinaria* spp and *Taenia* spp.

For the treatment of puppies and kittens infected with gastro-intestinal nematodes and puppies infected with protozoa (*Giardia* spp).

For the treatment of dogs infected with lungworm *Oslerus (Filaroides) osleri* or protozoa *Giardia* spp and cats infected with lungworm *Aelurostrongylus abstrusus*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral.

Read the package leaflet before use.

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

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Only treat puppies and kittens weighing greater than 1 kg with this product (see package leaflet).

Keep the syringe in the outer carton.

10. EXPIRY DATE

EXP end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

NFA-VPS

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive,
Magna Business Park
Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4448

17. MANUFACTURER'S BATCH NUMBER

Batch Number: {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Carton box/ Individual syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 187.5 mg/g Oral Paste for dogs and cats
Fenbendazole

2. STATEMENT OF ACTIVE SUBSTANCES

Fenbendazole 187.5 mg/g

3. PHARMACEUTICAL FORM

Oral Paste.

4. PACKAGE SIZE

1 syringe containing 4.8 g oral paste

5. TARGET SPECIES

Dogs, cats, puppies and kittens.

6. INDICATION(S)

Wormer for dogs, cats, puppies and kittens.

For the treatment of adult dogs and cats infected with gastro-intestinal nematodes and cestodes, including *Ascarid* spp (*Toxocara canis*, *Toxocara cati* and *Toxascaris leonina*), *Ancylostoma* spp, *Trichuris* spp, *Uncinaria* spp and *Taenia* spp.

For the treatment of puppies and kittens infected with gastro-intestinal nematodes and puppies infected with protozoa (*Giardia* spp).

For the treatment of dogs infected with lungworm *Oslerus (Filaroides) osleri* or protozoa *Giardia* spp and cats infected with lungworm *Aelurostrongylus abstrusus*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral.

Read the package leaflet before use.

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

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Only treat puppies and kittens weighing greater than 1 kg with this product (see package leaflet).

Keep syringe in outer carton.

10. EXPIRY DATE

EXP end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

NFA-VPS

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive,
Magna Business Park
Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4448

17. MANUFACTURER'S BATCH NUMBER

Batch Number: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Syringe Label }**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 187.5 mg/g Oral Paste for dogs and cats
Fenbendazole

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

187.5 mg/g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4.8 g

4. ROUTE(S) OF ADMINISTRATION

Oral.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

BN: {number}

7. EXPIRY DATE

EXP end of: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
Keep out of the sight and reach of children.

Vm 01708/4448

Keep syringe in outer carton.

NFA-VPS

PACKAGE LEAFLET FOR:
Panacur 187.5 mg/g Oral Paste for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 187.5 mg/g Oral Paste for dogs and cats
Fenbendazole

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

1 g of oral paste contains:

Active substance:

Fenbendazole 187.5 mg

Excipients:

Methyl hydroxybenzoate (E218) 0.17 mg
Propyl hydroxybenzoate 0.016 mg

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

4. INDICATION(S)

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. The product 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 gastrointestinal 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*.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Mild gastrointestinal signs in dogs and in cats (such as vomiting and diarrhoea) can occur in very rare cases.

The frequency of these adverse reactions after the use of this product is based on post marketing safety experience (pharmacovigilance).

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Dogs, cats, puppies and kittens.

8 . DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Adult Cats and Dogs

Orally administer 2 syringe graduations per 1 kg bodyweight as a single dose (= 100 mg fenbendazole/kg bodyweight). Each syringe is sufficient to dose up to 9 kg bodyweight as a single dose.

Practical dosage recommendations:

Bodyweight	Single dose
Up to 1 kg	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 breeder's premises.

Puppies and kittens under 6 months of age

Only treat puppies and kittens weighing greater than 1 kg with this product. Orally administer the recommended dosages as described below, daily for 3 consecutive days

Each syringe is sufficient to dose up to 6 kg bodyweight for 3 consecutive days.

Practical dosage recommendations:

Bodyweight	Daily dose for 3 days
1.0 - 2 kg	2 syringe graduations
2.1 - 3 kg	3 syringe graduations
3.1 - 4 kg	4 syringe graduations
4.1 - 5 kg	5 syringe graduations
5.1 - 6 kg	6 syringe graduations

Additional syringes are required if puppies weigh over 6 kg under 6 months old. 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/breeder's 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 cannot accurately be attained when using the syringe, it is recommended that alternative formulations of fenbendazole be used.

Pregnant cats

Pregnant cats can be safely treated with the product 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 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).

9. ADVICE ON CORRECT ADMINISTRATION

Panacur 187.5 mg/g Oral Paste should be administered orally by squeezing the paste from the syringe onto the back of the tongue after feeding.

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. To protect householders, discard any unused paste into tissue and immediately dispose of via the household waste. 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 body weight of the animal. Turn the ring on the plunger to the corresponding graduation.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.

Keep the syringe in the outer carton.

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.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight or misadministration of the product.

Special precautions for use in animals:

Assess bodyweight 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.
Wear impermeable rubber gloves while administering the product
Wash hands after use.

Pregnancy:

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 cannot accurately be attained when using the syringe, it is recommended that alternative formulations of fenbendazole be used.

Overdose (symptoms, emergency procedures, antidotes):

Benzimidazoles have a high margin of safety.

Incompatibilities:

None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2022

15. OTHER INFORMATION

For animal treatment only.
Pack sizes: cardboard box with 1 syringe or 10 syringes.
Not all pack sizes may be marketed.

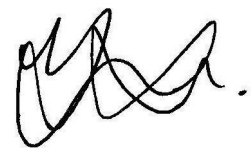
Legal category

NFA-VPS

Vm 01708/4448

Distributor in Northern Ireland:

Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24



Approved: 23 February 2022