

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Carton box/10x100 ml }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 10% Oral Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Panacur 10% is an oral suspension containing 100 mg fenbendazole per ml.

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

10x100 ml

1 L

2 L

5 L

10 L

5. TARGET SPECIES

Cats, dogs, kittens and puppies.

6. INDICATION(S)

Wormer for cats, dogs, kittens and puppies.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral suspension.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store at room temperature.
Keep the container in outer carton.
Do not freeze.

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

Read the 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

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

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4436

17. MANUFACTURER’S BATCH NUMBER

Batch No: {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton box/100 ml }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 10% Oral Suspension Small Animal.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Panacur Small Animal 10% oral suspension contains 100 mg Fenbendazole per ml.

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

10x100 ml

1 L

2 L

5 L

10 L

5. TARGET SPECIES

Cats, dogs, kittens and puppies.

6. INDICATION(S)

Wormer for cats, dogs, kittens and puppies.

Uses

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*, *Toxocaris leona*), Ancylostoma spp., Trichuris spp., Uncinaria spp. and 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral suspension.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY CONTRAINDICATIONS, WARNINGS...

Assess body weight as accurately as possible before calculating dosage.

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

Shake container well before use.

Do not freeze.

Keep the container in outer carton.

Direct contact with the skin should be kept to a minimum.

Wear impermeable rubber gloves and wash hands after use.

Disposal: read package leaflet.

10. EXPIRY DATE

EXP end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4436

17. MANUFACTURER'S BATCH NUMBER

Batch No: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Label/100 ml}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 10% Oral Suspension Small Animal

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Panacur Small Animal 10% oral suspension containing 100mg Fenbendazole per ml.

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

100 ml

1 L

2 L

5 L

10 L

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN: {number}

7. EXPIRY DATE

EXP End of: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Read package leaflet before use.

Contra-indications : None known.

Shake well before using.

Direct contact with the skin should be kept to a minimum.

Wear impermeable rubber gloves and wash hands after use.

Disposal: read package leaflet.

Do not freeze. Keep the container in outer carton.

For oral administration only.

Keep out of the sight and reach of children.

PACKAGE LEAFLET FOR:

Panacur Small Animal 10% Oral Suspension

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 Small Animal 10% Oral Suspension.

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

<u>Active substance</u>	<u>% w/v</u>
Fenbendazole	10.000
<u>Other substances</u>	
Sodium methyl hydroxybenzoate	0.200
Sodium propyl hydroxybenzoate	0.020
Benzyl alcohol	0.4835
A white oral suspension.	

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.

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 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.

5. CONTRAINDICATIONS

None known.

6. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Domestic dogs, cats, puppies and kittens.

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

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).

9. ADVICE ON CORRECT ADMINISTRATION

See pt. 8 above.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not freeze. Keep the container in the outer carton. Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Assess body weight as accurately as possible before calculating the dosage.

Use in 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.

User warnings:

Direct contact with the skin should be kept to a minimum. Wear impermeable rubber gloves and wash hands after use.

Other warnings:

The use of this 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. For animal treatment only.

Overdose:

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

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

April 2021

15. OTHER INFORMATION

Pack sizes

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

Legal category

NFA-VPS

Marketing authorisation number

Vm 01708/4436

Approved: 01/04/21



