

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/5 L}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 10% oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fenbendazole

3. PHARMACEUTICAL FORM

Oral suspension containing 100 mg fenbendazole per ml.

4. PACKAGE SIZE

10x100 ml

1x1L

1x2 L

1x5 L

1x10 L

5000 doses for 20 kg lambs, 2000 doses for 50 kg ewes

333 doses for 200 kg cattle, 111 doses for 600 kg horses

5. TARGET SPECIES

Cattle, sheep and horse wormer.

6. INDICATION(S)

For the treatment and control of gastro-intestinal roundworm infections in cattle, sheep and horses and of lungworm and tapeworm infections in cattle and sheep.

USES

Panacur 10 % suspension is a broad spectrum anthelmintic for the control of all major benzimidazole-susceptible species of gastro-intestinal roundworms, including *Ostertagia* spp., *Teldorsagia* spp. and *Nematodirus* spp., and lungworms affecting cattle and sheep. It is effective against the adult and immature stages of gastro-intestinal roundworms and lungworms and also kills roundworm eggs. Panacur 10 % suspension is also usually effective against Type II winter ostertagiasis in cattle and against *Moniezia* spp. of tapeworm in cattle and sheep. In horses and other equines,

Panacur 10 % suspension is effective against benzimidazole-susceptible large and small strongyles, ascarids, *Oxyuris* spp. and *Strongyloides* spp.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION

For oral administration only. Shake container well before use.

Cattle and Horses: 1ml per 13 kg bodyweight (7.5 mg fenbendazole per kg bodyweight) to be given orally (see table). For horses, mix the product with grain or concentrate feed and give the full dose as one administration. Pregnant mares and foals may be treated safely with fenbendazole at therapeutic levels. For the treatment of migrating larval and tissue stages of large strongyles and encysted stages of small strongyles in horses, the dose should be repeated daily for five days. Sheep: 0.5 ml per 10 kg bodyweight (5 mg fenbendazole per kg bodyweight) to be given orally (see table).

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Treatment should be repeated when reinfestation occurs.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS AND WARNINGS

Do not use in horses and other equines intended for human consumption.

Withdrawal periods: Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 12 days from the last treatment. Sheep may be slaughtered for human consumption only after 15 days from the last treatment. Milk from treated animals must not be taken for human consumption during treatment. Milk from treated cows may be taken for human consumption only after 5 days from the last treatment. Milk from treated sheep may be taken for human consumption only after 7 days from the last treatment.

Operator warnings: Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

Disposal advice: Dangerous to aquatic life. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with product or used containers.

Other warnings: Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, discuss dosing programmes with your veterinary surgeon.

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.
- Under dosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any). Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to benzimidazoles (which include fenbendazole) has been reported in *Teladorsagia*, *Haemonchus*, *Cooperia* and *Trichostrongylus* species in small ruminants in a number of countries, including the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Resistance to fenbendazole has been reported in cyathostomes in horses. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

10. EXPIRY DATE

EXP END OF: {month/year}

11. SPECIAL STORAGE CONDITIONS

Storage: Do not store above 25°C. Do not freeze. Protect from frost. Overdose: Benzimidazoles have a high margin of safety. No specific overdose symptoms are known. No specific actions required.

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

Dangerous to aquatic life. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with product or used containers.

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

[Distribution category]

POM-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

Distributed in Northern Ireland by
Intervet Ireland Ltd
Magna Drive, Magna Business Park, Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4435

17. MANUFACTURER’S BATCH NUMBER

BN: {number}

Do not mix with other products.

Instructions for use with automatic dosing equipment (e.g. Panacur® Drencher):

1. Remove the product container from the carton and shake well.
2. Attach plastic hook through a hole at the base of the bottle and tie strap through diagonally opposite hole at the top, making adjustments as necessary to allow the bottle to hang comfortably on the operator’s back.
3. With the product container in the upright position, remove the plain cap and pierce seal with the nozzle cap provided.
4. Screw nozzle cap tightly onto the bottle and firmly attach tube from the automatic dosing equipment to the nozzle. Class of anthelmintic: 1-BZ
5. Hang the bottle in the inverted position on the operator’s back and carefully prime the gun.

Part used packs may be kept. The nozzle cap should be replaced by the plain cap.

To be supplied only on veterinary prescription.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Front label/5L}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 10% oral suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fenbendazole

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

5000 doses for 20 kg lambs

2000 doses for 50 kg ewes

333 doses for 200 kg cattle

111 doses for 600 kg horses

10x100 ml

1x1L

1x2 L

1x5 L

1x10 L

4. ROUTE(S) OF ADMINISTRATION

Oral suspension.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Cattle, sheep and horse wormer

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Back label/5L}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur 10% oral suspension

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fenbendazole

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

	Practical Dosage Recommendations (Cattle and horses above 400kg should be given a further 5ml for each additional 65kg bodyweight)					
Weight of cattle / horses	65kg	135kg	200kg	265kg	335kg	400kg
Dose	5ml	10ml	15ml	20ml	25ml	30ml

Sheep: 0.5ml per 10kg bodyweight (5mg Fenbendazole per kg bodyweight) to be given orally.

	Practical Dosage Recommendations (Sheep above 60kg should be given a further 0.5ml for each additional 10kg bodyweight)					
Weight of sheep	10kg	20kg	30kg	40kg	50kg	60kg
Dose	0.5ml	1ml	1.5ml	2ml	2.5ml	3ml

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

4. ROUTE(S) OF ADMINISTRATION

Oral suspension.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN: {number}

7. EXPIRY DATE

EXP END OF: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

USES

Broad spectrum anthelmintic for the treatment and control of gastro-intestinal roundworm infections in cattle, sheep and horses and of lungworm and tapeworm infections in cattle and sheep.

DOSAGE AND ADMINISTRATION

For oral administration only. Shake container well before use.

Cattle and Horses: 1ml per 13 kg bodyweight (7.5 mg fenbendazole per kg bodyweight) to be given orally.

For horses, mix the product with grain or concentrate feed and give the full dose as one administration.

CONTRA-INDICATIONS AND WARNINGS

Do not use in horses and other equines intended for human consumption.

Withdrawal periods: Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 12 days from the last treatment.

Sheep may be slaughtered for human consumption only after 15 days from the last treatment.

Milk from treated animals must not be taken for human consumption during treatment.

Milk from treated cows may be taken for human consumption only after 5 days from the last treatment.

Milk from treated sheep may be taken for human consumption only after 7 days from the last treatment.

Operator warnings: Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves. Wash hands after use.

Disposal advice: Dangerous to aquatic life. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Do not contaminate ponds, waterways or ditches with product or used containers.

Other warnings: Intensive use or misuse of anthelmintics can give rise to resistance, see carton text. To reduce this risk, discuss dosing programmes with your veterinary surgeon. Do not mix with other products.

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

Keep out of the sight and reach of children.

Storage: Do not store above 25°C. Do not freeze.

Protect from frost. Keep container in its outer carton.

For further information on uses and dosing, please refer to the carton.

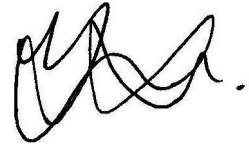
Legal category: POM-VPS To be supplied only on veterinary prescription.

Vm 01708/4435

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

Distributed in Northern Ireland by
Intervet Ireland Ltd
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

Cattle, sheep and horse wormer

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 30 December 2020