

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/225 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Guard with Apple & Cinnamon Flavour

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An aqueous suspension containing 10% w/v fenbendazole.

3. PHARMACEUTICAL FORM

10% w/v Oral Suspension

4. PACKAGE SIZE

225 ml bottle.

5. TARGET SPECIES

Equine.

6. INDICATION(S)

USES

For the treatment and control of migrating larval and tissue stages of large redworm; encysted mucosal 3rd and 4th stage small redworm larvae and encysted inhibited 3rd stage small redworm larvae in the mucosa of horses and other equines. (In late winter or spring, mass emergence of encysted mucosal small redworm can cause parasitic diarrhoea, mild recurring colic, listlessness, weakness, appetite and weight loss.)

This product is also effective in controlling other immature and mature roundworms including large redworm (*Strongylus edentatus* and *Strongylus vulgaris*) and migrating large redworm larvae, Ascarids, Oxyuris and Strongyloides species, and benzimidazole susceptible small strongyles (cyathostomes). Panacur also kills roundworm eggs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION

Administer 5ml of this product per 65kg bodyweight, daily for 5 consecutive days (7.5 mg fenbendazole/kg bodyweight daily for 5 days).

Treatment of encysted inhibited and encysted mucosal dwelling larvae should be performed in the autumn (ideally late October/November) and again in the Spring (ideally in February). Treatment with this product should form part of an integrated

worming plan. Consult your supplier for advice regarding wormers to use throughout the year. For horses who fail to maintain condition or bought-in horses with unknown worming history, the treatment can be given at any time of the year. No dietary control is required before or after the treatment.

DOSAGE RECOMMENDATIONS

Weight req.	Type	Daily Dose for 5 days	Total volume
Up to 300 kg	Donkeys,	25 ml	125 ml
	Shetlands,		
	Welsh Mountain etc.		
300-400 kg	Dartmoor, New Forest, Welsh and similar ponies.	30ml	150ml
450-600 kg	Thoroughbreds, Light Hunters, Arabs, etc.	45ml	225ml
Over 600 kg	Heavy Hunters, Draught Horses.	45ml + an extra 5ml for each additional 65 kg Bodyweight	225 ml

This product can be easily administered by mixing with your horse's grain/concentrate feed. Full daily dosage must be given as one administration. Assess your horse's bodyweight accurately before calculating dosage. Pregnant mares and young foals can be safely treated with Panacur at therapeutic dose levels. The use of a weigh band is recommended.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS OR WARNINGS

Not to be used in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impermeable rubber gloves.

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

FURTHER INFORMATION

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your veterinary surgeon.

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.

POM-VPS

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

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation 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 01708/4441

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

Group anthelmintic: 1-BZ

Legal category: POM-VPS

To be supplied only on veterinary prescription.

This bottle contains sufficient Panacur to treat a horse up to 600 kg bodyweight at the recommended dose.

Shake well before use and protect from freezing.

For the control of Encysted Inhibited and Encysted Mucosal small redworm.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Label/10x225 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Guard with Apple & Cinnamon Flavour

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

10% w/v

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

10 x 225 ml

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”

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

DO NOT FREEZE

To be supplied only on veterinary prescription.

Legal category: POM-VPS

For the control of Encysted Inhibited and Encysted Mucosal small redworm.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Label/225 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Guard with Apple & Cinnamon Flavour

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

An aqueous suspension containing 10% w/v fenbendazole

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

225 ml

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"

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

For uses, dosage, contra-indications and warnings - see package leaflet.

Not to be used in horses intended for human consumption, see package leaflet for full warning.

Keep container in outer carton.

Protect from freezing.

To be supplied only on veterinary prescription.

Legal category: POM-VPS

For the control of Encysted Inhibited and Encysted Mucosal small redworm.

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

Distributed in Northern Ireland by:
Intervet Ireland Ltd, Dublin 24

Vm 01708/4441

Group anthelmintic: 1-BZ
Legal category: POM-VPS
To be supplied only on veterinary prescription.

PACKAGE LEAFLET FOR:

Panacur Equine Guard with Apple & Cinnamon Flavour

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Guard with Apple & Cinnamon Flavour.

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

10% w/v Oral Suspension.

4. INDICATION(S)

USES

For the treatment and control of adult and immature roundworms of the gastrointestinal tract in horses and other equines. The product is effective for the treatment and control of encysted mucosal 3rd and 4th stage small strongyle larvae and is also effective against encysted inhibited 3rd stage small strongyle larvae in the mucosa. The product is also effective in controlling other immature and mature roundworms including large redworm (*Strongylus edentatus* and *Strongylus vulgaris*) and migrating large redworm, Ascarids (*Parascaris equorum*), Oxyuris and Strongyloides species and benzimidazole susceptible adult and immature small strongyles. Fenbendazole also has an ovicidal effect on nematode eggs.

5. CONTRAINDICATIONS

CONTRA INDICATIONS, WARNINGS, ETC.

Withdrawal periods:

Not to be used in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

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.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

FOR ANIMAL TREATMENT ONLY.

Environmental warnings

Dangerous to fish and aquatic life.

Dispose of any unused product and empty containers in accordance with guidance from your local waste authority.

Do not contaminate ponds, waterways or ditches with product or used container.

General warnings

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed 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 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.

PHARMACEUTICAL WARNINGS

Protect from freezing. Shake container before use.

Mix the medicated feed thoroughly prior to administration, for example by rolling the drum or barrel.

Liquid feed containing Panacur Equine Guard will remain stable for up to 3 months. Keep container in outer carton.

6. ADVERSE REACTIONS

7. TARGET SPECIES

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

DOSAGE AND ADMINISTRATION

No dietary control is required before or after treatment.

For the treatment and control of migrating and tissue larval stages of large strongyles, encysted mucosal 3rd and 4th stage small strongyle larvae and encysted inhibited 3rd stage small strongyle larvae in the mucosa administer 5ml per 65kg bodyweight daily for 5 days (= 7.5 mg fenbendazole/kg bodyweight daily for 5 days). The product can be easily administered by mixing with grain or concentrate feed. The full daily dosage must be given as one administration.

Pregnant mares and foals may also be safely treated with fenbendazole at therapeutic dosage levels.

Assess bodyweight as accurately as possible before calculating the dosage. The use of a 'weigh band' is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

Recommended dosing programme

Treatment of encysted inhibited and encysted mucosal dwelling larvae should be performed in the autumn (ideally late October/November) and again in the Spring (ideally in February).

However, for horses who fail to maintain condition or bought-in horses with unknown worming history, the treatment can be given at any time of the year.

Treatment with this product should form part of an integrated worming plan. Consult with your supplier for advice regarding wormers to use throughout the year.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

12. SPECIAL WARNING(S)

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020.

15. OTHER INFORMATION

Vm 01708/4441

LEGAL CATEGORY POM-VPS

To be supplied only on veterinary prescription.

PACKAGE QUANTITIES

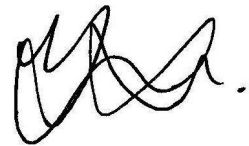
225 ml multidose containers.

FURTHER INFORMATION

Panacur has been extensively used for the treatment of worm infestations in exotic animal species. For further information on suggested dose rates, please contact the Veterinary advisor of the Company.

Fenbendazole belongs to the benzimidazole (1 BZ) class of anthelmintics.

Studies have indicated that inhibited 3rd stage small strongyle larvae represent 50% of the total larval population in the horse.

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

Approved: 30 December 2020