

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Guard 10% w/v

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

An aqueous suspension containing fenbendazole 10% w/v.

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

225 ml bottle.

5. TARGET SPECIES

6. INDICATION(S)

Horse wormer.

For the control of encysted inhibited and encysted mucosal small redworm.

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.)

Panacur® Equine Guard 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 5 ml Panacur Equine Guard per 65 kg 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 should form part of an integrated worming plan. Consult your supplier for advice regarding other wormers to use during 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 |
| 300-400 kg | Shetlands, Welsh Mountain etc. 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 |

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS OR WARNINGS

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

Dangerous to fish and aquatic life.

Do not contaminate ponds, waterways or ditches with the product or used containers. Dispose of empty packaging and any remaining product in the household refuse.

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

Keep the container in the outer carton.

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]

To be supplied only on veterinary prescription.

| |
|---------|
| 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 01708/4466

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

1-BZ

Panacur Equine Guard 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.

For the control of encysted inhibited and encysted mucosal small redworm

5 DAY COURSE

An aqueous suspension containing fenbendazole 10% w/v.

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

Shake well before use. Do not freeze.

FOR ANIMAL TREATMENT ONLY.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {Label/10 x 225 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Guard 10% w/v

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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.

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

HORSE WORMER.

Keep out of reach and sight of children.

For animal treatment only.

Do not freeze.

To be supplied only on veterinary prescription.

POM-VPS

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

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2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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"

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HORSE WORMER.

Keep out of reach and sight of children.

For animal treatment only.

Do not freeze.

To be supplied only on veterinary prescription.

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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

Group anthelmintic: 1-BZ

PACKAGE LEAFLET FOR:

Panacur EQUINE GUARD 10% w/v Oral suspension

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

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

Distributed in Northern Ireland by:

INTERVET IRELAND Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur EQUINE GUARD 10% w/v Oral suspension

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

PRESENTATION

A 10% w/v suspension of Fenbendazole as a ready to administer oral anthelmintic for horses. Panacur Equine Guard contains 10% w/v active ingredient Fenbendazole.

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. Panacur Equine Guard also has an ovicidal effect on nematode eggs.

5. CONTRAINDICATIONS

CONTRA-INDICATIONS, WARNINGS ETC.

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.

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 (= 7.5mg 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.

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

PHARMACEUTICAL PRECAUTIONS

Do not freeze. 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 10% w/v will remain stable for up to 3 months.

Keep container in outer carton.

12. SPECIAL WARNING(S)

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.

Environmental warnings:

Dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with product or used container.

Dispose of empty packaging and any remaining product in the household refuse.

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.

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Date of text preparation: December 2020.

15. OTHER INFORMATION

Vm 01708/4466

KEEP OUT OF REACH AND SIGHT OF CHILDREN.
FOR ANIMAL TREATMENT ONLY.
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.

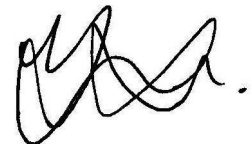
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Approved: 30 December 2020