

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/ 10 x 24 g syringes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur equine oral paste 18.75% w/w

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 24 g syringe contains 4.5 g fenbendazole.

3. PHARMACEUTICAL FORM

Horse wormer – oral syringe application

4. PACKAGE SIZE

10 x 24 g syringes

Contains 10 syringes each containing 24 g Panacur Equine Paste.

Each syringe of paste contains 4.5 g fenbendazole.

5. TARGET SPECIES

Equine.

6. INDICATION(S)

PRESENTATION

Panacur Equine Oral Paste 18.75% w/w is a ready-to-administer, oral paste wormer for horses and other equines.

INDICATIONS

A broad spectrum anthelmintic for the treatment and control of adult and immature roundworms of the gastro-intestinal tract in horses and other equines. Panacur also has an ovicidal effect on nematode eggs.

Panacur effectively treats and controls the following roundworm infections:

Large strongyles (adults and migrating larval stages of *S.vulgaris*; adults and tissue larval stages of *S.edentatus*).

Benzimidazole susceptible adult and immature small strongyles (*Cyathostomes*), including encysted mucosal 3rd and 4th stage larvae; it is also effective against encysted inhibited 3rd stage larvae in the mucosa.

Adult and immature *Oxyuris* spp., *Strongyloides* spp. and *Parascaris equorum*.

Dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

METHOD AND ROUTE OF ADMINISTRATION

Panacur Equine Paste should be administered orally by squeezing the paste from the syringe onto the back of the tongue. No dietary control is required before or after treatment.

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

Recommended dosing programme

All horses should be routinely wormed with the single dose of Panacur Equine Paste every 6-8 weeks.

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 which fail to maintain condition or bought-in horses with unknown worming history, the treatment can be given at any time of the year. See package leaflet for practical dosing recommendations.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS AND WARNINGS

Read package leaflet before use.

10. EXPIRY DATE

EXP END OF: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Store syringe in outer carton.

Protect from direct sunlight.

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.

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

Vm 01708/4439

17. MANUFACTURER’S BATCH NUMBER

BN: {number}

FOR USES, DOSAGE, CONTRAINDICATIONS AND DISPOSAL WARNING, SEE PACKAGE LEAFLET.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/ 24 g syringes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur equine oral paste 18.75% w/w

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Panacur Equine Oral Paste 18.75% w/w is a ready-to-administer, oral paste for horses and other equines. Each 24g syringe contains 4.5 g fenbendazole.

3. PHARMACEUTICAL FORM

Horse wormer – oral syringe application

4. PACKAGE SIZE

24 g syringes

5. TARGET SPECIES

Equine.

6. INDICATION(S)

INDICATIONS

A broad spectrum anthelmintic for the treatment and control of adult and immature roundworms of the gastro-intestinal tract in horses and other equines. Panacur also has an ovicidal effect on nematode eggs.

Panacur effectively treats and controls the following roundworm infections:

Large strongyles (adults and migrating larval stages of *S.vulgaris*; adults and tissue larval stages of *S.edentatus*).

Benzimidazole susceptible adult and immature small strongyles (Cyathostomes), including encysted mucosal 3rd and 4th stage larvae; it is also effective against encysted inhibited 3rd stage larvae in the mucosa.

Adult and immature *Oxyuris* spp., *Strongyloides* spp. And *Parascaris equorum*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

METHOD AND ROUTE OF ADMINISTRATION

Panacur Equine Paste should be administered orally by squeezing the paste from the syringe onto the back of the tongue. No dietary control is required before or after treatment.

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

Recommended dosing programme

All horses should be routinely wormed with the single dose of Panacur Equine Paste every 6-8 weeks.

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

See package leaflet for practical dosing recommendations.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:

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

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

Disposal warnings:

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

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

SPECIAL WARNINGS

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.

10. EXPIRY DATE

EXP END OF: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from direct sunlight. Keep syringe in 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]

For animal treatment.

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

Vm 01708/4439

17. MANUFACTURER’S BATCH NUMBER

BN: {number}

To be supplied only on veterinary prescription.

FOR USES, DOSAGE, CONTRAINDICATIONS AND DISPOSAL WARNING, SEE
PACKAGE LEAFLET.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur equine oral paste 18.75% w/w

With Apple & Cinnamon Flavour

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 24 g syringe contains 4.5 g fenbendazole

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

4. ROUTE(S) OF ADMINISTRATION

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

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN: {number}

7. EXPIRY DATE

EXP END OF: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

Do not administer to horses intended for human consumption

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Do not store above 25 °C. Protect from direct sunlight.

MA Holder: MSD Animal Health UK Ltd.,

Walton Manor, Walton, Milton Keynes MK7 7AJ

Distributed in Northern Ireland by: Intervet Ireland Ltd, Dublin 24. Keep syringe in outer carton. To be supplied only on veterinary prescription.

Legal category: POM-VPS

PACKAGE LEAFLET FOR:
Panacur equine oral paste 18.75% w/w

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 for the batch release:
Intervet Productions S.A.
Rue de Lyon
27460 Igoville
Bucks. France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur equine oral paste 18.75% w/w

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

Fenbendazole 18.75 w/w per 24 g syringe. A white to light grey homogenous oral paste.

4. INDICATION(S)

A broad spectrum anthelmintic for the treatment and control of adult and immature roundworms of the gastro-intestinal tract in horses and other equines. Panacur also has an ovicidal effect on nematode eggs.

Panacur effectively treats and controls the following roundworm infections:

Large strongyles (adults and migrating larval stages of *S.vulgaris*; adults and tissue larval stages of *S.edentatus*).

Benzimidazole susceptible adult and immature small strongyles (Cyathostomes), including encysted mucosal 3rd and 4th stage larvae; it is also effective against encysted inhibited 3rd stage larvae in the mucosa.

Adult and immature *Oxyuris* spp., *Strongyloides* spp. and *Parascaris equorum*.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known. If you notice any serious effects or other effects not mentioned in this

leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses and other equines.

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

Routine treatment: Administer orally, 1 Syringe per 600 kg bodyweight
(= 7.5 mg fenbendazole/kg bodyweight)

Practical dosage recommendations:

Up to 100kg	Miniature ponies	Syringe mark 100kg
101 to 300kg	Donkey, shetland and other small ponies & foals	Syringe mark 300kg (½ syringe)
301 to 400kg	Dartmoor, New Forest	Syringe mark 400kg
<i>Welsh</i>		
401 to 500kg	Light hunters, Arabs etc	Syringe mark 500kg
501 to 600kg	Thoroughbreds	Syringe mark 600kg (1 syringe)
601kg and over	Heavy hunters, draught horses	1 full syringe plus additional 100kg syringe marks for each extra 100kg bodyweight

Increased dosing for specific infections:

Five day course:

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 1 syringe per 600 kg bodyweight daily for 5 days. (= 7.5 mg fenbendazole/kg bodyweight daily for 5 days)

Single dose treatments:

For the treatment and control of encysted mucosal stages of small strongyles administer

1 syringe per 150 kg bodyweight. (= 30 mg fenbendazole/kg bodyweight)

For the treatment and control of migrating stages of large strongyles administer 1 syringe per 75 kg bodyweight. (= 60 mg fenbendazole/kg bodyweight)

For the treatment and control of *Strongyloides westeri* in sucking foals administer 1 syringe per 90 kg bodyweight. (= 50 mg fenbendazole/kg bodyweight)

Panacur Equine Paste should be administered orally by squeezing the paste from the syringe onto the back of the tongue. No dietary control is required before or after treatment.

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

Recommended dosing programme

All horses should be routinely wormed with the single dose of Panacur Equine Paste every 6-8 weeks.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Assess bodyweight as accurately as possible before calculating the dosage.

10. WITHDRAWAL PERIOD(S)

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children. Do not store above 25 °C. Protect from direct sunlight.

12. SPECIAL WARNING(S)

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.

For animal treatment only.

USER WARNINGS

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

Wear impermeable rubber gloves while administering the product.

Wash hands after use.

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

Dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. 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: 24 g syringes and packs of 10 x 24g syringes.

POM-VPS

To be supplied only on veterinary prescription.

Vm 01708/4439

Distributed in N. Ireland by:

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

Approved: 01/04/21



