PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/10x10x2.2g }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Granules 22.2% w/w

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram of granules contains 0.22 g fenbendazole

3. PHARMACEUTICAL FORM

Granules

4. PACKAGE SIZE

Contains 10 boxes each containing 10 sachets of 10.2 g Panacur Equine Granules.

5. TARGET SPECIES

Equine.

6. INDICATION(S)

Horse wormer.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

USES

A broad spectrum wormer for the treatment of horses and other equines infected with benzimidazole susceptible immature and mature large redworms (*Strongylus vulgaris*, *S. edentatus*) and migrating large redworms, small redworm including mucosal stages, Ascarids, Oxyuris and Strongyloides. Also kills roundworm eggs. DOSAGE AND ADMINISTRATION

Routine treatment: One sachet per 300 kg bodyweight as a single dose. Control of migrating large redworm larvae and encysted mucosal small redworm: One sachet per 300 kg bodyweight daily for five consecutive days.

Sprinkle granules onto the horse's grain or concentrate feed with the fully daily dosage given in one feed.

Treatment should be repeated when natural reinfestation with worms occurs. For further information on uses, dosage and administration and warnings: see package leaflet.

ROUTINE TREATMENT: PRACTICAL DOSAGE RECOMMENDATIONS

Weight	Туре	Dosage
Up to 300 kg	Donkeys, Shetland and other small ponies etc.	1 sachet
300-600 kg	Larger Ponies, Thoroughbreds, Light Hunters, Arabs, etc.	2 sachets
Over 600 kg	Heavy Hunters, Draught Horses.	3 sachets

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS AND WARNINGS

Not to be used in horses intended for human consumption, see package leaflet for full warnings. Avoid inhalation of granule dust.

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

Wash hands after use. Dispose of used containers/sachets safely.

Asses bodyweight accurately before calculating the dosage. Pregnant mares and young foals may be safely treated with Fenbendazole at therapeutic dosage levels. This veterinary medicinal product does not require any special storage conditions.

10. EXPIRY DATE

EXP END OF: {month/year}

11. SPECIAL STORAGE CONDITIONS

Dispose of any unused product or empty sachets in accordance with guidance from your local waste regulation authority.

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

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 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 01708/4424

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/ 10 x 10.2g sachets}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Granules 22.2% w/w

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram of granules contains 0.22g fenbendazole

3. PHARMACEUTICAL FORM

Granules

4. PACKAGE SIZE

10 x 10.2g sachets

5. TARGET SPECIES

Equine.

6. INDICATION(S)

Horse wormer

7. METHOD AND ROUTE(S) OF ADMINISTRATION

USES

A broad spectrum wormer for the treatment of horses and other equines infected with benzimidazole susceptible immature and mature large redworms (*Strongylus vulgaris*, *S. edentatus*) and migrating large redworms, small redworm including mucosal stages, Ascarids, Oxyuris and Strongyloides. Also kills roundworm eggs. DOSAGE AND ADMINISTRATION

Routine treatment: One sachet per 300 kg bodyweight as a single dose.

Control of migrating large redworm larvae and encysted mucosal small redworm: One sachet per 300 kg bodyweight daily for five consecutive days.

Sprinkle granules onto the horse's grain or concentrate feed with the fully daily dosage given in one feed.

Treatment should be repeated when natural reinfestation with worms occurs. For further information on uses, dosage and administration and warnings: see pack leaflet. This veterinary medicinal product does not require any special storage conditions.

Weight	Туре	Dosage
Up to 300 kg	Donkeys, Shetland and other small ponies etc.	1 sachet
300-600 kg	Larger Ponies, Thoroughbreds, Light Hunters, Arabs, etc.	2 sachets
Over 600 kg	Heavy Hunters, Draught Horses.	3 sachets

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS AND WARNINGS

Not to be used in horses intended for human consumption, see package leaflet for full warning. Avoid inhalation of granule dust.

Direct contact with the product should be kept to a minimum. Wash hands after use. Dispose of used containers/sachets safely.

Asses bodyweight accurately before calculating the dosage. Pregnant mares and young foals may be safely treated with Fenbendazole at therapeutic dosage levels. When sold individually, sachets should be accompanied by a leaflet.

10. EXPIRY DATE

EXP end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of any unused product or empty sachets in accordance with guidance from your local waste regulation authority.

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, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4424

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Label/ 10.2 g sachet}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Granules 22.2% w/w

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

White granules containing 0.22 g fenbendazole per gram.

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

10.2 g sachet

4. ROUTE(S) OF ADMINISTRATION

DOSAGE AND ADMINISTRATION

Routine treatment: One sachet per 300 kg bodyweight as a single dose.

Control of migrating large redworm larvae and encysted mucosal small redworm:

One sachet per 300 kg bodyweight daily for five consecutive days.

Sprinkle granules onto the horse's grain or concentrate feed with the fully daily dosage given in one feed.

Treatment should be repeated when natural reinfestation with worms occurs.

For further information on uses, dosage and administration and warnings: see pack leaflet.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN: {number}

7. EXPIRY DATE

EXP END OF: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

USES

A broad spectrum wormer for the treatment of horses and other equines infected with benzimidazole susceptible immature and mature large redworms (*Strongylus vulgaris*, *S. edentatus*) and migrating large redworms, small redworm including mucosal stages, Ascarids, Oxyuris and Strongyloides.

Also kills roundworm eggs.

CONTRA-INDICATIONS AND WARNINGS

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

Avoid inhalation of granule dust.

Direct contact with the product should be kept to a minimum. Wash hands after use. Dispose of used containers/sachets safely.

Asses bodyweight accurately before calculating the dosage. Pregnant mares and young foals may be safely treated with Fenbendazole at therapeutic dosage levels.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Keep sachets in outer carton. This veterinary medicinal product does not require any special storage conditions.

Dispose of any unused product or empty sachets in accordance with guidance from your local waste regulation authority.

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.

Vm 01708/4424

Legal category: POM-VPS

To be supplied only on veterinary prescription

PACKAGE LEAFLET FOR:

Panacur Equine Granules 22.2% w/w

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

Licensed distributor for Northern Ireland Intervet Ireland Ltd. Magna Drive, Magna Business Park Citywest Road, Dublin 24

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Equine Granules 22.2% w/w

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

Presentation

Panacur Equine Granules is a ready to administer oral wormer for horses and other equines. Each sachet contains 2.2 g Fenbendazole per 10.2 g granules.

4. INDICATION(S)

Uses

For the treatment of horses and other equines infected with benzimidazole susceptible immature and mature stages of roundworms found in the gastrointestinal tract, including large redworms (*Strongylus vulgaris*, *Strongylus edentatus*) and migrating large redworms, small redworm and mucosal larvae, *Ascarids*, *Oxyuris* and *Strongyloides* species. Panacur also kills roundworm eggs.

5. CONTRAINDICATIONS

Contra-indications and warnings

Direct contact with the skin should be avoided. Wash hands after use. Dispose of any unused product or empty sachets in accordance with guidance from your local waste regulation authority. Dangerous to fish and aquatic life. Do

not contaminate ponds, waterways or ditches with the product or used container. Avoid inhalation of granule dust.

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.

6. ADVERSE REACTIONS

7. TARGET SPECIES

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

Dosage and administration

Routine treatment: One sachet per 300 kg bodyweight as a single dose.

Practical dosage recommendations:

Weight	Туре	Dosage
Up to	eg. Donkeys, Shetlands, and other	1 sachet
300 kg	small ponies, etc.	
300 - 600 kg	Larger ponies, Thoroughbreds,	2 sachets
	Light hunters, Arabs etc.	
600 kg +	Heavy hunters, Draught horses	3 sachets

9. ADVICE ON CORRECT ADMINISTRATION

Increased dosing for specific infections

For the control of migrating large redworm and encysted mucosal small redworm larvae, administer one sachet per 300 kg bodyweight daily for 5 consecutive days. It is not necessary to withhold feed before or after treatment. Assess bodyweight accurately before calculating the dosage. The use of a weigh band is recommended.

Panacur Equine Granules are odourless and tasteless and should be mixed with your horse's concentrate or grain feed with the full daily dosage given in one feed.

Dosing programmes

It is recommended that horses and ponies are routinely wormed up to every six to eight weeks during the grazing season, depending on their individual requirements. Seek veterinary advice for appropriate monitoring, stock management and dosing programmes to allow optimum endoparasite control.

In late winter or spring, mass emergence of mucosal small redworm larvae from the horse's gut can cause parasitic diarrhoea, mild recurring colic, weight and appetite loss and weakness. To avoid this, it is recommended that horses are treated with the 5 day Panacur treatment between the end of October and December.

All new horses whose worming history is unknown should also be treated with the 5 day Panacur dose.

Pregnant mares and foals may also be safely treated with Panacur at recommended dosage levels.

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

Pharmaceutical precautions

This veterinary medicinal product does not require any special storage condition. Keep sachets in outer carton.

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

Date of text preparation: December 2020

15. OTHER INFORMATION

Product licence number: Vm 01708/4424

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

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

Packaging quantities: 10x10.2g sachets

Further information: Nil

Approved: 30 December 2020