PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Tub}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine Granules

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 37.5 g sachet contains:	
Trimethoprim	2.5 g
Sulfadiazine	12.5 g

3. PHARMACEUTICAL FORM

Granules

4. PACKAGE SIZE

10 x Sachets

5. TARGET SPECIES

Horses

6. INDICATION(S)

For the treatment of bacterial infections in horses. Norodine is a broad spectrum antibacterial, active against a wide range of Gram-positive and Gram-negative organisms. Together the active ingredients produce a double blockade of folinic acid resulting in a level of activity much greater than obtained from either drug alone. *In vitro* Norodine is effective against *Escherichia coli*, *Rhodococcus equi*, *Staphylococci* and *Streptococcus* spp.

When susceptible organisms are present, may be effective in treating the following conditions:

Alimentary tract infections including diarrhoea.

Respiratory tract infections including pneumonia, pleurisy and strangles.

Wounds, septicemia and general infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The daily dose is 30 mg combined active ingredients per kg bodyweight daily, (5 mg trimethoprim and 25 mg sulfadiazine per kg bodyweight). Treatment should be continued for up to 5 days or until 2 days after symptoms have resolved.

After careful estimation of the weight of the horse, the required dose of Norodine granules should be mixed with the horse' feed prior to administration. Add to feed immediately before administration. Discard any remaining medicated feed.

Dosage Guide:

	DAILY DOSE	
BODYWEIGHT	Weight of Norodine Granules	No. of Scoops
100 kg	7.5 g	½
200 kg	15 g	1
300 kg	22.5 g	1½
400 kg	30 g	2
500 kg	37.5 g	Whole Sachet

Each sachet contains one daily dose for a 500 kg horse. The scoop provided dispenses 15 g of granules.

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

Do not use in horses with known sulphonamide sensitivity, with hepatic damage or with blood dyscrasias.

Avoid inhalation and take care to avoid skin and eye contact. Gloves and suitable eye protection should be worn whilst handling this product. Wash hands and exposed skin after use.

Sulphonamides may cause severe allergic reactions. See package leaflet for full operator warnings.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C.

Any unused drug remaining in opened sachets after the last treatment should be discarded.

Keep the container in the outer carton.

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

Dispose of unused product, unused medicated feed and empty containers 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]*

POM-V

For animal treatment only. To be supplied only on veterinary prescription.

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

Norbrook Laboratories Limited

Station Works

Newry

Co. Down

N. Ireland BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4114

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Sachet}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine Granules

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 37.5 g sachet contains:

Trimethoprim	2.5 g
Sulfadiazine	12.5 g

3. PHARMACEUTICAL FORM

Granules

4. PACKAGE SIZE

10 x Sachets each sachet containing 37.5 g of Norodine Granules

5. TARGET SPECIES

Horses

6. INDICATION(S)

Norodine is a broad spectrum antibacterial, active against a wide range of Gram-positive and Gram-negative organisms. Each sachet contains one daily dose for a 500 kg horse.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration to horse after mixing with feed. 30 mg combined active ingredients per kg bodyweight daily, (5 mg trimethoprim and 25 mg sulfadiazine per kg bodyweight). Treatment should be continued for up to 5 days or until 2 days after symptoms have resolved.

Add to feed immediately before administration. Discard any remaining medicated feed.

Dosage Guide:

	DAILY DOSE	
BODYWEIGHT	Weight of Norodine Granules	No. of Scoops

100 kg	7.5 g	½
200 kg	15 g	1
300 kg	22.5 g	1½
400 kg	30 g	2
500 kg	37.5 g	Whole Sachet

The scoop provided dispenses 15 g of granules.

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

Do not use in horses with known sulphonamide sensitivity, with hepatic damage or with blood dyscrasias.

Avoid inhalation and take care to avoid skin and eye contact. Gloves and suitable eye protection should be worn whilst handling this product. Wash hands and exposed skin after use.

Sulphonamides may cause severe allergic reactions. See package leaflet for full operator warnings.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C.

Any unused drug remaining in opened sachets after the last treatment should be discarded.

Keep the container in the outer carton.

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

Dispose of unused product, unused medicated feed and empty containers 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]*

POM-V

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

Station Works

Newry

Co. Down

N. Ireland BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4114

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

Norbrook Laboratories Limited

Station Works

Newry

Co. Down

N. Ireland BT35 6JP

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine Granules

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

Each sachet contains 37.5g of product containing:

Trimethoprim 2.5g

Sulfadiazine 12.5g

4. INDICATION(S)

For the treatment of bacterial infections in horses. Norodine is a broad spectrum antibacterial, active against a wide range of Gram-positive and Gram-negative organisms. Together the active ingredients produce a double blockade of folinic acid resulting in a level of activity much greater than obtained from either drug alone. *In vitro* Norodine is effective against *Escherichia coli*, *Rhodococcus equi*, *Staphylococci* and *Streptococcus* spp.

When susceptible organisms are present Norodine Granules may be effective in treating the following conditions:

Alimentary tract infections including diarrhoea.

Respiratory tract infections including pneumonia, pleurisy and strangles.

Wounds, septicemia and general infections.

5. CONTRAINDICATIONS

Do not use in horses with known sulfonamide sensitivity, with hepatic damage or with blood dyscrasias.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon

7. TARGET SPECIES

Horses

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

The daily dose is 30 mg combined active ingredients per kg bodyweight daily, (5 mg trimethoprim and 25 mg sulfadiazine per kg bodyweight). Treatment should be continued for up to 5 days or until 2 days after symptoms have resolved.

Dosage Guide:

	DAILY DOSE	
BODYWEIGHT	Weight of Norodine Granules	No. of Scoops
100 kg	7.5 g	½
200 kg	15 g	1
300 kg	22.5 g	1½
400 kg	30 g	2
500 kg	37.5 g	Whole Sachet

Each sachet contains one daily dose for a 500 kg horse. The scoop provided dispenses 15 g of granules.

9. ADVICE ON CORRECT ADMINISTRATION

After careful estimation of the weight of the horse, the required dose of Norodine granules should be mixed with the horse' feed prior to administration. Add to feed immediately before administration. Discard any remaining medicated feed.

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

Do not store above 25ºC.

Any unused drug remaining in opened sachets after the last treatment should be discarded.

Keep the container in the outer carton.

12. SPECIAL WARNING(S)

Avoid inhalation and take care to avoid skin and eye contact. Gloves and suitable eye protection should be worn whilst handling this product. Wash hands and exposed skin after use.

Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.
2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

For Animal Treatment Only

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

Dispose of unused product, unused medicated feed and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 02000/4114

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

Approved: 10/01/2018