PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NORODINE EQUINE ORAL PASTE

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each syringe contains 45 g of oral paste containing:

Trimethoprim	5.80 %w/w
Sulfadiazine	28.83 %w/w

3. PHARMACEUTICAL FORM

Oral Paste.

4. PACKAGE SIZE

3 x 45g dial-a-dose Syringe.

5. TARGET SPECIES

Horses.

6. INDICATION(S)

For the treatment of bacterial infections in horses.

Norodine Equine Paste may be effective in treating the following conditions. Alimentary tract infections including diarrhoea. Respiratory tract infections including pneumonia, pleurisy and strangles. Wounds, septicaemia and general infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The daily dose is 30 mg combined active ingredients per kg bodyweight. Each syringe provides one daily dose for a 500 kg horse. Each division on the dial-a-dose plunger provides sufficient product to treat 50 kg of bodyweight.

Treatment should be continued for up to five days or until two days after symptoms have resolved. Drug absorption may be greater if food is withheld for a few hours prior to dosing.

Adjust screw gauge on dial-a-dose plunger to the bodyweight of the horse. Remove cap from nozzle. Place nozzle in corner of mouth. Depress plunger depositing paste on upper surface of tongue. Replace cap after use.

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

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

Do not use in cases of known hypersensitivity, severe hepatic dysfunction or cardiac arrhythmias. Do not use the same syringe to treat more than one animal unless horses are running together or in direct contact with each other on the same premises.

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.

10. EXPIRY DATE

Exp: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from freezing.
Keep syringe in outer carton.

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

Dispose of any unused product and empty syringes 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-V

To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA: 2000

Vm: 02000/4098

17. MANUFACTURER’S BATCH NUMBER

Bn.:
D.O.M.:

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NORODINE EQUINE ORAL PASTE

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

oral paste containing:
Trimethoprim 5.80 %w/w
Sulfadiazine 28.83 %w/w

3. PHARMACEUTICAL FORM

Oral Paste.

4. PACKAGE SIZE

45 g

5. TARGET SPECIES

Horses.

6. INDICATION(S)

Norodine Equine Paste is a broad spectrum antibacterial active against a wide range of Gram-positive and Gram-negative organisms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration to horses.
The daily dose is 30 mg combined active ingredients per kg bodyweight. Each syringe provides one daily dose for a 500 kg horse. Each division on the plunger provides sufficient product to treat 50 kg of bodyweight. Treatment should be continued for up to five days or until two days after symptoms have resolved.

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

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

Do not use the same syringe to treat more than one animal unless horses are running together or in direct contact with each other on the same premises.
Wash hands after use.

User warnings. Sulphonamides may occasionally cause severe allergic reactions. See carton for full user warnings.

10. EXPIRY DATE

Exp.: dd/mm/yyyy

11. SPECIAL STORAGE CONDITIONS

DO NOT STORE ABOVE 25°C.
PROTECT FROM FREEZING.
KEEP SYRINGE IN OUTER CARTON

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

Dispose of any unused product and empty syringes 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-V

To be supplied only by veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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16. MARKETING AUTHORISATION NUMBER(S)

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DOM:

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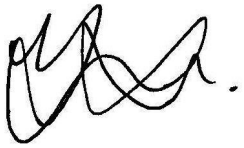

Approved: 28 October 2022