SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NORODINE EQUINE ORAL PASTE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

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

Excipients:

Methyl Parahydroxybenzoate	0.18 %w/w
Propyl Parahydroxybenzoate	0.02 %w/w

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Paste.
A creamy white paste for oral administration.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

Indicated in the treatment of bacterial infections in horses caused by sensitive microorganisms including:

Escherichia coli
Rhodococcus (Corynebacterium) equi
Staphylococcus spp
Streptococcus spp

The product may be effective in alimentary tract infections including diarrhoea, respiratory infections including pneumonia, pleurisy, strangles, wounds, septicaemia and general infections.

4.3 Contra-indications

None.

4.4 Special Warnings for each target species

No special precautions.

4.5 Special precautions for use

Special precautions for use in animals

Use of the following product should be based on susceptibility testing and take into account official and local antimicrobial policies. Not recommended in horses with 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

4.6 Adverse reactions (frequency and seriousness)

No undesirable effects.

4.7 Use during pregnancy, lactation or lay

Can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Drug absorption may be greater if food is withheld for a few hours prior to dosing.

4.9 Amounts to be administered and administration route

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

The daily dose is 30 mg of combined actives per kg bodyweight by oral administration. Treatment should be continued for up to 5 days or until 2 days after symptoms have resolved.
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.

Replace cap after use.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No treatment specified.

4.11 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial

ATC Vet Code: QJ01EW10

5.1 Pharmacodynamic properties

Sulfadiazine (SDZ) inhibits the incorporation of para-aminobenzoic acid into folic acid and trimethoprim (TMP) inhibits the enzyme dihydrofolate reductase (DHFR) which converts dihydrofolic acid into tetrahydrofolic acid. (TMP) and (SDZ) act together synergistically with a double-blockage mode of action. The combination is bactericidal inhibiting sequential steps in the synthesis of purines which are required for DNA synthesis. TMP-SDZ combinations have a broad bactericidal action against many gram-positive and gram-negative aerobic bacteria and a large proportion of anaerobic bacteria.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Propylene Glycol
Carbomer (974P NF)
Sodium Hydroxide Solution 20%
Water for Injection

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25°C. Protect from freezing.

6.5 Nature and composition of immediate packaging

White high density polyethylene disposable dial-a-dose syringes with white high density polyethylene, push-fit caps containing 45 g of product. Available in boxes of 3 syringes.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4098

9. DATE OF FIRST AUTHORISATION

19 January 1988

10. DATE OF REVISION OF THE TEXT

February 2020

Approved: 10 February 2020