1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine Equine Oral Paste.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active Substances

Trimethoprim	58 mg
Sulfadiazine	288.3 mg

Excipients

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl Parahydroxybenzoate (E218)	1.8 mg
Propyl Parahydroxybenzoate (E216)	0.2 mg
Propylene Glycol	
Carbomers	
Sodium Hydroxide	
Purified Water	

A creamy white paste.

3. CLINICAL INFORMATION

3.1 Target Species

Horses.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated in the treatment of bacterial infections in horses caused by sensitive microorganisms including:

Escherichia coli
Staphylococcus spp.
Streptococcus spp.

3.3 Contraindications

Do not use in horses with known sulphonamide sensitivity and also in animals with hepatic damage or blood dyscrasias.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

To ensure a correct dosage, body weight should be determined as accurately as possible.
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 30mg of combined actives per kg bodyweight by oral administration. Treatment should be continued until 2 days after symptoms have resolved, up to a maximum of 5 days.
Each syringe contains enough for one daily dose for a 500 kg horse.**3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**
Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12. Withdrawal periods

Meat and offal: 28 days.

Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QJ01EW10

4.2 Pharmacodynamics

Sulfadiazine (SDZ) inhibits the incorporation of para-aminobenzoic acid into folic acid and trimethoprim (TMP) inhibits the enzyme dihydrofolate reductase (DHFR) which coverts 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, a large proportion of anaerobic bacteria, chlamydia and protozoa.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf-life

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

5.3 Special precautions for storage

Do not store above 25 °C.
Do not freeze.

5.4 Nature and composition of immediate packaging

Immediate packaging: The veterinary medicinal product is presented in a white high density polyethylene oral syringe with a high density polyethylene plunger calibrated in divisions, each equivalent to 50 kg of bodyweight and a white high density polyethylene cap (push-fit).

Outer packaging and sales presentations:
- Cartons of 3 syringes.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/019/01

8. DATE OF FIRST AUTHORISATION

01/10/1988

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

22/03/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).