SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine Granules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Each 37.5g sachet contains:

Trimethoprim	2.5g
Sulfadiazine	12.5g

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules
White to off-white granules.

4. CLINICAL PARTICULARS

4.1 Target species

Horse

4.2 Indications for use, specifying the target species

Recommended in the treatment of infections in horses caused by organisms sensitive to trimethoprim/ sulfadiazine combinations.

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.

4.3 Contraindications

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

4.4 Special Warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

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

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.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

The use of trimethoprim-sulfadiazine combinations during pregnancy and lactation has not been shown to cause any adverse effects or foetal abnormalities.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For oral administration by addition to feeds. The recommended dose is 30 mg of combined active product per kg bodyweight daily, (5 mg trimethoprim and 25 mg sulfadiazine per kg). 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

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

There is no known specific antidote, if signs of possible overdose occur, treat symptomatically.

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 for systemic use.

ATC Vet Code: QJ01EW10

5.1 Pharmacodynamic properties

The trimethoprim-sulfadiazine combination derives its activity from the fact that the drugs act together with a unique "double blockade" of action. Each drug inhibits a different step in the biosynthetic pathways used by micro-organisms in the synthesis of reduced folate co-factors. Sulfadiazine inhibits the incorporation of para-aminobenzoic acid into folic acid and trimethoprim greatly potentiates the antimicrobial activity of sulphonamides both *in vitro* and *in vivo*, resulting in a synergistic effect. The combination presents a broad spectrum of antibacterial activity against Gram-positive and Gram-negative bacteria. In vitro the product is effective against *Escherichia coli*, *Rhodococcus equi*, *Staphylococci* and *Streptococcus* spp.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone (K30)
Sodium Starch Glycollate
Lactose Anhydrous

6.2 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^{O}C.

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

6.5 Nature and composition of immediate packaging

Aluminium foil sachets supplied with a 25ml/15g polypropylene scoop.

Cartons of 10 sachets, each sachet containing 37.5 g of product.

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
Newry
Co. Down
N. Ireland BT35 6JP

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4114

9. DATE OF FIRST AUTHORISATION

10th December 1993

10. DATE OF REVISION OF THE TEXT

February 2009