1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine Bolus Tablet.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Each tablet contains:

Trimethoprim	200 mg
Sulfadiazine	1.0 g.

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

3. PHARMACEUTICAL FORM

Tablet.
A white bolus-shaped tablet, deeply scored on one face.

4. CLINICAL PARTICULARS

4.1 Target species

Calves

4.2 Indications for use, specifying the target species

Norodine Bolus is indicated primarily for the treatment of bacterial scours but may also be used for the treatment of acute salmonellosis and bacterial pneumonia.

4.3 Contraindications

Norodine Bolus should not be administered to animals with functionally mature rumens.

4.4 Special Warnings for each target species

No special precautions.

4.5 Special precautions for use

Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.

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

Take care to avoid skin and eye contact. Protective gloves 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)

None.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.9 Amounts to be administered and administration route

Oral: One tablet per 40 kg bodyweight daily. This gives 30 mg of combined active ingredients per kg bodyweight.
Treatment should be repeated daily until two days after the symptoms have resolved, but in cases of salmonellosis and bacterial pneumonia treatment should be continued for 5 consecutive days. Treatment must not be continued for more than 5 days.

The product may be administered whole, by hand or balling gun, or dispersed in water. Dosage by dispersion in water: Disperse each bolus by shaking in about 300 ml of water in dosing bottle. This may be facilitated by crushing the bolus before placing it in the bottle. After dosing by this method any unused material should be discarded.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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

Not applicable.

4.11 Withdrawal period

Meat: 15 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use.

ATC Vet Code: QJ01EW10

5.1 Pharmacodynamic properties

Sulphadiazine (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

Lactose Monohydrate
Maize Starch
Cellulose microcrystalline
Magnesium Stearate
Water Purified

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 25ºC.
Store in a dry place.
Protect from light.

6.5 Nature and composition of immediate packaging

White or grey polypropylene 'securitainers', closed with white, low density polyethylene, tamper evident lids. Each container contains 20 or 50 tablets.

Not all pack sizes may be marketed.

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, BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4079

9. DATE OF FIRST AUTHORISATION

17th December 1986.

10. DATE OF REVISION OF THE TEXT

December 2008.