Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine Bolus

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5.6g tablet contains

Active Substances

Trimethoprim 200 mg
Sulphadiazine 1.0 g

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

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.
Do not administer to animals with known hypersensitivity to the active ingredients.
Do not use in animals with severe liver or kidney parenchymal damage or 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 of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal produsct to animals
None.

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 interactions

None known.

4.9 Amounts to be administered and administration route

Norodine Bolus may be administered whole by hand or by balling gun.
One bolus per 40 kg bodyweight daily. This gives 30 mg of combined active ingredients per kg bodyweight.
To ensure correct dosage body weight should be determined as accurately as possible.
Treatment should be repeated daily until two days after the clinical signs have resolved, up to a maximum of five days.
In cases of salmonellosis and bacterial pneumonia treatment must be continued for 5 consecutive days.

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

Not applicable.

4.11 Withdrawal period(s)

Meat and offal: 14 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, sulfadiazine and trimethoprim.
ATCvet 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, a large proportion of anaerobic bacteria, chlamydia and protozoa.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize Starch
Microcrystalline Cellulose
Magnesium Stearate

6.2 Major incompatibilities

Not applicable

6.3 Shelf-life

3 Years

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

White or grey polypropylene ‘securitainers’ containing 20 or 50 white oval shaped tablets, deeply scored on one side and marked ‘NORBROOK’

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

January 2019