SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimacare Tablets Bolus

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Each tablet contains
Trimethoprim 200 mg
Sulphadiazine 1.0g.

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

3. PHARMACEUTICAL FORM

Tablet
An 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

The product 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 Contra-indications

Not to 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

Use of the product should be based on susceptability 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 bateria.

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 are sensitive to sulphonamides.
2. If you develop symptoms following exposure such as a skin rash, you should seek medical advise 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

One tablet per 40 kg bodyweight daily, orally. 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 tablet by shaking in about 300 ml of water in dosing bottle. This may be facilitated by crushing the tablet before placing it in the bottle. After dosing by this method any unused material should be discarded.

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

Diaminopyrimidines have a wide safety margin and sulphonamide toxicity is rare in animals.

4.11 Withdrawal period

Calves: meat – 15 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sulfadiazine & Trimethoprim

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-blockade 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 25°C.
Store in a dry place.
Protect from light.

6.5 Nature and composition of immediate packaging

White or grey high density polypropylene 'securitainers', containing 20 or 50 scored white tablet shaped tablets, closed with white low density tamper evident polyethylene lids.

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: 02000/4148

9. DATE OF FIRST AUTHORISATION

15th May 1998

10. DATE OF REVISION OF THE TEXT

October 2008