SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimacare 20 Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each tablet contains :
Trimethoprim 20mg
Sulfadiazine 100 mg.

Excipients:

Titanium dioxide (E171). *0.27 mg
* Denotes approximate amounts

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
Off-white, sugar-coated, unscored, circular tablets

4. CLINICAL PARTICULARS

4.1 Target species

Dogs
Adult Cats

4.2 Indications for use, specifying the target species

When susceptible organisms are present the combination may be effective in treating alimentary tract infections, respiratory and urogenital infections, skin and wound infections, and eye and ear infections where susceptible organisms are present.

4.3 Contra-dindications

None known.

4.4 Special Warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

The tablets should not be divided.

When given to cats the tablets should not be crushed before administration.

Maintain adequate fluid intake during treatment.

Not to be used in cases of hepatic renal impairment or blood dyscrasia

Wherever possible, use of Trimacare should be based on susceptibility testing.

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

Take care to avoid skin contact.
Wash hands 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)

A low incidence of polyarthropathy and Keratoconjunctivitis Sicca (Dry Eye) has been reported in dogs following oral administration of potentiated sulphonamides. If either of these conditions occurs, it is recommended that medication is stopped and that future treatment with similar products is avoided.

Sulphonamide sensitivity is rare in companion animals but should be considered in cases of unexpected responses to treatment.

4.7 Use during pregnancy, lactation or lay

Can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer orally by hand. The daily dose is 30 mg of combined active ingredient per kg bodyweight. This is achieved using the following doses;

Dogs and adult cats: 1 tablet per 4 kg bodyweight.

Treatment should be continued for up to 5 days or until 2 days after symptoms have subsided.

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

No treatment specified.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sulfadiazine & Trimethoprim.

ATC Vet Code: QJ01EW10

5.1 Pharmacodynamic properties

Sulfadiazine (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.
Sulphonamides are absorbed rapidly after oral administration and diffuse rapidly into tissues. Elimination is mainly by metabolism in the liver and excretion in the urine. Trimethoprim also diffuses well into body tissues and though eliminated quicker, the combination remains active for sufficient time to achieve effective antimicrobial activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium Dioxide (E171).
Cellulose microcrystalline,
Lactose Monohydrate,
Sodium Starch Glycollate,
Povidone (K17),
Magnesium Stearate,
Sucrose,
Talc Purified,

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 25ºC.
Store in a dry place.
Protect from light.

6.5 Nature and composition of immediate packaging

White polypropylene securitubs sealed with a white low density polyethylene push fit, tamper evident cap.

Available in containers of 100 tablets.

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 form 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: 02000/4146

9. DATE OF FIRST AUTHORISATION

15th January 1998

10. DATE OF REVISION OF THE TEXT

October 2008