SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimacare 80 Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each tablet contains:
Trimethoprim 80 mg
Sulfadiazine 400 mg.

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
White circular uncoated tablets scored on one side.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

Not suitable for use in cats.

4.4 Special Warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals
Wherever possible, use of Trimacare should be based on suceptability testing.

Not to be used in cases of hepatic or renal impairment, or blood dyscrasia. Maintain adequate fluid intake during treatment.

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 hypersensitivty (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these subatances 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)

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 occur, it is recommended that medication is stopped and that future treatment 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

The daily dose is one tablet per 16 kg bodyweight administered orally, providing 30 mg of combined active ingredients per kg bodyweight. Treatment should be continued for up to five 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: Sulfonamides & Trimethropim

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 and 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

Cellulose Microcrystalline,
Povidone (K30),
Lactose Monohydrate,
Sodium Stearate Glycollate,
Magnesium Stearate.

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.
The tablets are packaged in quantities of 100 and 500 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: 02000/4147

9. DATE OF FIRST AUTHORISATION

21st January 1998

10. DATE OF REVISION OF THE TEXT

October 2008