Part II
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimedoxine 80 Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Trimethoprim 80mg and Sulfadiazine 400mg.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

When susceptible organisms are present, the product 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

Trimedoxine 80 tablets are not suitable for use in cats.

4.4 Special warnings for each target species

No special warnings.

4.5 Special precautions for use

(i) Special precautions for use in animals

No special precautions.

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

Wash hands after use.

If accidental ingestion occurs, seek medical advice immediately.
For animal treatment only

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 with similar products is avoided.

Sulphonamide hypersensitivity 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 safety administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.9 Amounts to be administered and administration route

The daily dose is one tablet per 16kg bodyweight administered orally, providing 30mg of combined active ingredients per 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(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QJ01EW10

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 and bactericidal action against many gram-positive and gram-negative aerobic bacteria and a large proportion of anerobic bacteria.

Bioavailability of SDZ after oral administration is good, with a plasma half-life of about 4 hours. TMP is well absorbed after oral administration, with a shorter half-life. Antibacterial synergism occurs

over a wide range of dose combinations. Both substances are metabolised in the liver and excreted largely in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Povidone
Lactose monohydrate
Sodium starch 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

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

6.5 Nature and composition of immediate packaging

White circular tablets scored on one side.

The tablets are stored in white polypropylene securitubs sealed with a white polyethylene cap. The tablets are packaged in quantities of 100 and 500 tablets.

Not all pack sizes are 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

Vétoquinol UK Limited
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8. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4055

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11 May 1994/11 May 2004

10. DATE OF REVISION OF THE TEXT

December 2007