SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Co Trimazine Tablets 480 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains

Active Substance(s):	**mg :**
Trimethoprim	80
Sulfadiazine	400

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet.
A circular, uncoated, white tablet scored on one face.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

When susceptible organisms are present the Tablets 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 Contraindications

Co-trimazine Tablets 480 mg 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

Use of the product should be based on susceptibility testing of 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.

ii. 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 reaction with other antibiotics. Allergic reactions to these substances 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 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 sulfonamides. If either of these conditions occur, it is recommended that medication is stopped and that future treatment is avoided.
Sulfonamide 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

No known interactions.

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.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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

No treatment specified.

4.11 Withdrawal period

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sulfonamides

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose,
Povidone (K12),
Lactose monohydrate,
Sodium Starch Glycollate, Type A,
Magnesium stearate.

6.2 Incompatibilities

Not applicable

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 25^{O}C.
Store in a dry place.
Protect from light.

6.5 Nature and composition of immediate packaging

White opaque polypropylene tub with a white opaque polyethylene cap (push fit) (tamper evident) containing either 100 or 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 product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Listow Limited
9 Belgrave Square
London
SW1X 8PH

8. MARKETING AUTHORISATION NUMBER(S)

Vm 41687/4004

9. DATE OF FIRST AUTHORISATION

Date: 28 August 1997

10. DATE OF REVISION OF THE TEXT

Date: October 2012