SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **L-Trim Tablet**

1.2 Generic Name : Trimethoprim & Sulphamethoxazole Tablets BP

1.3 Strength : 80 mg & 400 mg per Tablet

1.4 Pharmaceutical Form: Tablet

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each uncoated tablet contains

Trimethoprim	BP	80mg
Sulphamethoxazole	BP	400mg

3. PHARMACEUTICAL FORM

Oral Tablet

White coloured round shaped, flat beveled uncoated tablet having central breakline one face of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Renal and urinary tract infections and chronic cystitis, pyelonephritis, urethritis.

Upper and lower respiratory tract infections such as acute and chronic bronchitis, bronchiectasis, and bronchopneumonia, tonsilitis, sinusitis, pharyngitis and otitis media.

Genital infections in both sex, including gonococcal urethritis.
G.I. tract infection: Enteritis, typhoid and paratyphoid fever, cholera, bacillary dysentery.
Skin infections: Pyoderma furuncles, abscesses and infected wounds some infections such as septicemia, osteomyelitis, other infections caused by sensitive organisms eg. brucellosis, hocardiosis, etc**.**

4.2 Posology and method of administration

Adults: L-Trim tablet two tablets twice daily.
Daily for at least five days or until the patient is symptom free for two days.

4.3 Contraindications:

The sulphonamides are contraindicated in patients with the history of sulpha hypersensitivity and advanced kidney diseases with elevated blood urea nitrogen. Caution is required inpatients with liver diseases, blood dyscrasias and impaired kidney function. Pregnant womanshould not receive sulphonamides because of possible placental transmission to the foetus and danger of kernicterus.

4.4 Special warnings and special precautions for use:

In patients with impaired renal function thedosage should be reduced and the interval between doses be prolonged in order toprevent cumulation in blood. The concentration of active ingredients in the plasmashould be determined in these patients. Indiscriminate use of Co-trimoxazole forcommon conditions may lead to serious blood disorders.

4.5 Interaction with other FPPs and Other forms of Interaction

In elderly patients concurrently receiving certain diuretics, primarily thiazides, an increasedincidence of thrombocytopenia with purpura has been reported. It has been reported that sulfamethoxazole; may prolong the prothrombin time in patients who are receiving theanticoagulant warfarin. This interaction should be kept in mind when sulfamethoxazole; trimethoprim is given to patients already on anticoagulant therapy, and the coagulation time should be reassessed. Sulfamethoxazole; trimethoprim may inhibit the hepatic metabolism of phenytoin. Sulfamethoxazole; trimethoprim, given at a common clinical dosage, increased thephenytoin half-life by 39% and decreased the phenytoin metabolic clearance rate by 27%. When administering these drugs concurrently, one should be alert for possible excessive phenytoin effect. Sulfonamides can also displace methotrexate from plasma protein binding sites, thus increasing free methotrexate concentrations.

4.6 Pregnancy and lactation

Contraindicated in pregnancy

4.7 Effects on ability to drive and use machines

None reported

4.8 Undesirable effects

At the recommended dosage Co-trimoxazole is wellb tolerated. Nausea, vomiting and skin rashes can occur. Purpura or agranulocytosis, may occur in isolated cases, both are reversible on withdrawal of the drug. Allergic reactions of the skin include urticaria, skin eruptions or acute hypersensitivity state.

4.9 Overdose

Nausea, vomiting, dizziness and confusion are likely signs/ symptoms of overdosage. If vomiting has not occurred, induction of vomiting may be desirable. Gastric lavage may be useful, though absorption from the gastrointestinal tract is normally very rapid and complete within approximately two hours. This may not be the case in gross overdosage. Dependant on the status of renal function administration of fluids is recommended if urine output is low. Both trimethoprim and active sulfamethoxazole are moderately dialysable by haemodialysis. Peritoneal dialysis is not effective.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Mechanism of action:

Co-trimoxazole is an antibacterial drug composed of two active principles, sulfamethoxazole and trimethoprim. Sulfamethoxazole is a competitive inhibitor of dihydropteroate synthetase enzyme. Sulfamethoxazole competitively inhibits the utilisation of para-aminobenzoic acid (PABA) in the synthesis of dihydrofolate by the bacterial cell resulting in bacteriostasis. Trimethoprim reversibly inhibits bacterial dihydrofolate reductase (DHFR), an enzyme active in the folate metabolic pathway converting dihydrofolate to tetrahydrofolate. Depending on the conditions the effect may be bactericidal. Thus trimethoprim and sulfamethoxazole block two consecutive steps in the biosynthesis of purines and therefore nucleic acids essential to many bacteria.

5.2 Pharmacokinetic properties

Absorption: After oral administration trimethoprim and sulfamethoxazole are rapidly and nearly completely absorbed. Peak levels in the blood occur between one and four hours after ingestion and the level attained is dose related.

Distribution: Approximately 50% of trimethoprim in the plasma is protein bound.

Metabolism: Renal excretion of intact sulfamethoxazole accounts for 15-30% of the dose. This drug is more extensively metabolised than

trimethoprim, via acetylation, oxidation or glucuronidation. Over a 72 hour period, approximately 85% of the dose can be accounted for in the urine as unchanged drug plus the major (N4-acetylated) metabolite.

Elimination : The half-life of trimethoprim in man is in the range 8.6 to 17 hours in the presence of normal renal function.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
1	Starch (Maize)	BP
2	Sodium Methyl Hydroxybenzoate	BP
3	Sodium Propyl Hydroxybenzoate	BP
4	Gelatin	BP
5	Povidone (PVPK-30)	
6	Talcum	BP
7	Magnesium Stearate	BP
8	Colloidal Anhydrous Silica	BP
9	Sodium Starch Glycollate	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30^{0}C. Protect from light. Keep away from moisture.

6.5 Nature and contents of container

10 Blisters of 10 tablets packed in an inner carton. (10 x 10)
100 blisters of 10 tablets packed in an inner carton. (10 x 100)

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER
AMD/12/2002&AMD/6/2002:

a) Date of first authorization: 21/01/1989.

b) Date of latest renewal: 01/01/2018.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
01/01/2023

10. DATE OF REVISION OF THE TEXT
01/01/2023