1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC) - Enclosed

SULFATRIM

(Co-Trimoxazole Tablets BP)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SULFATRIM (Co-Trimoxazole Tablets BP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chemical Name	Approved Name (if any)	Quantity / Tablet (mg)	Active / Non - active
4-Amino-*N*-(5-methylisoxazol-3-yl) benzenesulphonamide.	Sulfamethoxazole BP	400.00	Active Ingredient
5-(3,4,5-Trimethoxybenzyl) pyrimidine-2,4-diamine	Trimethoprim BP	80.00	Active Ingredient
Excipients			
sodium dodecyl sulphate	Sodium Lauryl Sulphate BP	2.750	Surfactant
---------	*Maize Starch BP	25.970	Diluent
---------	*Maize Starch (For Paste) BP	25.740	Binder
Methyl 4-hydroxybenzoate	Methyl Hydroxybenzoate BP	0.400	Antimicrobial Preservative
Propyl 4-hydroxybenzoate	Propyl Hydroxybenzoate BP	0.200	Antimicrobial Preservative
--------	Sodium Starch Glycolate BP	5.900	Disintegrant
---------	Purified Talc BP	3.850	Glidant
--------	Maize Starch BP	7.730	Diluent
---------	Magnesium Stearate BP	1.940	Lubricant

* Include 8.0 % additional quantity to compensate for LOD.

Definitions:

BP: British Pharmacopoeia

3. PHARMACEUTICAL FORM

Tablets (Oral)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SULFATRIM is indicated for the treatment of

Infections of the upper and lower respiratory tract: Acute or chronic bronchitis, bronchiectasis, pneumonia, tonsillitis, sinusitis, pharyngitis, otitis media.

Infections of the kidneys and urinary tracts: Acute or chronic cystitis, pyeitis, pyelocystitis, pyelonephritis, urethritis. Infection of the genital organs of men and women including gonococcal urethritis. Infections of the digestive tract Enteritis, typhoid, and paratyphoid (above all for the treatment of carrier states of germs). Infections of the skin: Pyodermas, furuncles, abscess and infected wounds.

4.2 Posology and method of administration

Two Sulfatrim tablet two times a day. Or as directed by the physician.

Sulfatrim is taken during or after meals. In case of acute infection, administer Sulfatrim for at least 5 days.

Method of administration: Oral use.

4.3 Contraindications

Sulfatrim not suitable for those patients having hypersensitivity to any of the components, severe renal / hepatic damage, serious hematological disorders.

4.4 Special warnings and precautions for use

General - should be given with caution to patients with impaired renal or hepatic function, to those with possible folate deficiency (e.g., the elderly, chronic alcoholics, patients receiving anticonvulsant therapy, patients with malabsorption syndrome, and patients in malnutrition states), and to those with severe allergy or bronchial asthma. In glucose-6-phosphate dehydrogenase-deficient individuals, hemolysis may occur.

Geriatric - In those concurrently receiving certain diuretics, primarily thiazides, an increased incidence of thrombocytopenia with purpura has been reported. Appropriate dosage adjustments should be made for patients with impaired kidney function.

4.5 Interaction with other medicinal products and other forms of interaction

Cyclosporine: Decreases efficacy and increases nephrotoxicity.

Methotrexate: Bone marrow depressant effect is potentiated. Phenytoin: Half-life is prolonged.

Sulponylureas: Increases hypoglycemic effect.

Oral contraceptives: Failure of oral contraceptives.

4.6 Pregnancy and lactation

Sulfatrim is contra-indicated during pregnancy. If the latter cannot be excluded, it is necessary to weigh the possible risk in considerations of the expected therapeutic benefit.

Use in Nursing mother - Sulfatrim is not safe for nursing mothers.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Adverse reactions associated with the administration of Sulfatrim, although rare, have occurred due to severe reactions, including stevens-johnson syndrome, toxic epidenmal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia and other blood dyscrasias. Side effects of Sulfatrim are headache, sore tongue, rash *1* itching, diarrhoea, jaundice, nausea, vomiting, purpura, leukopenia, thrombocytopenia, megaloblastic anaemia, pseudomembranous colitis.

4.9 Overdose

Signs and symptoms of overdosage reported with sulfonamides include anorexia, colic, nausea, vomiting, dizziness, headache, drowsiness, and unconsciousness. Pyrexia, hematuria, and crystalluria may be noted. Blood dyscrasias and jaundice are potential late manifestations of overdosage. Signs of acute overdosage with trimethoprim include nausea, vomiting, dizziness, headache, mental depression, confusion, and bone marrow depression.

General principles of treatment include the institution of gastric lavage or emesis; forcing oral fluids; and the administration of intravenous fluids if urine output is low and renal function is normal. Chronic: Use of Sulfatrim at high doses and/or for extended periods of time may cause bone marrow depression manifested as thrombocytopenia, leukopenia, and/or megaloblastic anemia. If signs of bone marrow depression occur, the patient should be given leucovorin; 5 to 15 mg leucovorin daily has been recommended by some investigators.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological category: Combinations of sulfonamides and trimethoprim, incl. derivatives;

ATC Code: J01EE01

5.1 Pharmacodynamic properties

Sulfatrim has bactericidal effect which result from the blockage of two catalysing enzymes of successive reactions in the biosynthesis of folic acid in the micro-organism. It encompasses Gram-positive and Gram-negative germs such as streptococci, pneumooocci, meningococcal, gonococci, bordetella, salmonellas, klebsiella / aerobacter, shigellae and vibrio cholerae.

5.2 Pharmacokinetic properties

	Sulfamethoxazole	Trimethoprim
• Absorption - oral	85%	> 95%
• Plasma Half Life		
mean	9 hours	10 hours
Range	5.9-19.7 hours	8.6-17 hours
• Volumetric Distribution	12 - 13 L/Kg	70- 100 L/Kg
• Plasma protein binding	66%	42 - 46%
• Elimination	Via urine	Via urine

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate BP, Methyl Hydroxybenzoate BP, Propyl Hydroxybenzoate BP, Sodium Lauryl Sulfate BP, Sodium Starch Glycolate BP, Maize Starch BP, Purified Talc BP.

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

Blister pack of 10 Tablets. Such 100 filled blister are packed in a printed carton along with a leaflet.

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC,

30th Floor, Almas Towers,

Shalina Healthcare DMCC, Dubai, UAE.

Jumeirah Lakes Towers Dubai-UAE.

8. MARKETING AUTHORISATION NUMBER

Application for granting new registration certificate

9. DATE OF FIRST AUTHORISATION

Application for granting new registration certificate

10. DATE OF UPDATE OF TEXT

July 2022