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Package Insert

CO-TRIMOXAZOLE TABLETS B.P.

POM

COMPOSITION:

Each uncoated tablet contains:

Trimethoprim B.P.	80 mg
Sulphamethoxazole B.P.	400 mg
Excipients	Q.S.

PHARMACOLOGICAL CLASSIFICATION:

Sulfonamide antibiotic

PHARMACOLOGICAL ACTION:

Trimethoprim blocks the production of tetrahydrofolic acid from dihydrofolic acid by binding to and reversibly inhibiting the required enzyme, dihydrofolate reductase. Sulfamethoxazole inhibits bacterial synthesis of dihydrofolic acid by competing with para-aminobenzoic acid (PABA). Thus, Sulfamethoxazole and Trimethoprim combination blocks two consecutive steps in the biosynthesis of nucleic acids and proteins essential to many bacteria.

Pharmacokinetics: *Absorption:* Peak blood levels for the individual components occur 1 to 4 hours after oral administration.

Distribution: Trimethoprim also distributes to bronchial secretions, and both pass the placental barrier and are excreted in human milk. Approximately 44% of Trimethoprim and 70% of Sulfamethoxazole are bound to plasma proteins.

Metabolism and Excretion: The average percentage of the dose recovered in urine from 0 to 72 hours after a single oral dose is 84.5% for total sulfonamide and 66.8% for free Trimethoprim. The mean serum half-lives of Sulfamethoxazole and Trimethoprim are 10 and 8 to 10 hours, respectively.

INDICATIONS:

Co-trimoxazole tablets are indicated for the treatment of the following infections

Treatment and prevention of *Pneumocystis jirovecii* (*P. carinii*) pneumonitis, Treatment and prophylaxis of toxoplasmosis, Treatment of nocardiosis, Acute uncomplicated urinary tract infection, Acute otitis media, Acute exacerbation of chronic bronchitis.

CONTRAINDICATIONS:

Hypersensitivity, It should not be used in patients suffering from liver parenchymal damage, or a severe renal insufficiency, during pregnancy, lactation & patients with megaloblastic anaemia or blood dyscrasias.

SPECIAL PRECAUTIONS AND WARNING:

Use with caution in Asthma Blood disorders, Decreased kidney function, Decreased liver function, Elderly people, Infants under 6 weeks of age, Lack of the enzyme G6PD in the blood.

Pregnancy: Co- Trimoxazole Tablets not recommended in pregnant women, particularly in the first trimester, unless clearly necessary

Lactation: Co- Trimoxazole Tablet is not recommended in breast-feeding women.

DOSAGE AND DIRECTIONS FOR USE:

Method of administration: oral

Adult and children over 12 years: Two tablets twice a day, morning and evening, after meals.

Maximum dose (for severe cases): Three tablets twice a day.

Children from 6 to 12 years: One tablet twice a day, morning and evening, after meals.

ADVERSE EFFECTS:

Headache, Rash, Diarrhoea, Blood disorders, Pain in the muscles (myalgia), Seizures (convulsions), Nausea and vomiting, Severe blistering skin reaction affecting the tissues of the eyes, mouth, throat and genitals. (Stevens-Johnson Syndrome), Inflammation of the lining of the mouth (stomatitis), Damage to the liver, Damage to the kidneys.

DRUG INTERACTIONS:

Phenytoin: Trimethoprim may inhibit metabolism of phenytoin or other hydantoins.

Procainamide: Trimethoprim may inhibit renal elimination of procainamide and its metabolites.

Sulfonylureas: May increase hypoglycemic response to sulfonylureas because of displacement from protein-binding sites or inhibition of hepatic metabolism.

OVERDOSAGE:

Nausea, vomiting, headaches, cyanosis, oliguria or anuria.

Both trimethoprim and active sulfamethoxazole are moderately dialysable by haemodialysis. Peritoneal dialysis is not effective.

PRESENTATION:

Blister / Jar pack

STORAGE INSTRUCTIONS:

Store in a cool, dry place.

Manufactured by :

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