Co-trimoxazole Tablets BP

POM

COMPOSITION:
Each uncoated tablet contains:

Sulfamethoxazole BP	800 mg
Trimethoprim BP	160 mg
Excipients	Q.S.

PHARMACOLOGICAL CLASSIFICATION:
Sulfonamide antibiotic

PHARMACOLOGICAL ACTION:
Trimethoprim blocks production of tetrahydrofolic acid from dihydrofolic acid by binding to and reversibly inhibiting dihydrofolatereductase.Sulfamethoxazole inhibits bacterial synthesis of dihydrofolic acid by competing with para-aminobenzoic acid (PABA). Thus, combination blocks two consecutive steps in biosynthesis of nucleic acids and proteins essential to many bacteria.
Pharmacokinetics:
Rapidly absorbed orally and peak blood levels within 1 to 4 hours. Distributed to sputum, vaginal fluid, and middle ear fluid; bronchial secretions, and pass placental barrier and excretedin human milk.Approximately 44% of Trimethoprim and 70% of Sulfamethoxazole are bound to plasma proteins. Metabolism of Sulfamethoxazole occurs predominately by N4-acetylation, although glucuronide conjugate has been identified. Principal metabolites of Trimethoprim are 1- and 3-oxides and the 3'- and 4'-hydroxy derivatives. Excretion is primarily by kidneys. Average percentage of dose recovered in urine from 0 to 72 hours after single oral dose is 84.5% for total sulfonamide and 66.8% for free Trimethoprim.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
- Nocardiosis, acute uncomplicated urinary tract infection (UTI), acute otitis media and acuteexacerbation of chronic bronchitis
- Treatment and prevention of Pneumocystis jiroveci pneumonitis and toxoplasmosis.

CONTRAINDICATIONS:
In patient with a history of hypersensitivity to sulphonamides, trimethoprim, co-trimoxazole or any excipients of co-trimoxazole, marked liver parenchymal damage, severe renal insufficiency, premature babies nor to full-term infants during the first 6 weeks of life.

SPECIAL PRECAUTIONS AND WARNING:
- Rare fatalities due to severe reactions including fulminant hepatic necrosis, agranulocytosis, aplastic anaemia, other blood dyscrasias and hypersensitivity of respiratory tract. Life-threatening cutaneous reactions Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported.
- Elderly patients group with impaired kidney and/or liver function and/or concomitant use of other drugs, patients at risk of acute porphyria or serious haematological disorders or receiving cytotoxic therapy or at risk of hyperkalaemia.
- Raresulphonamide crystals observedin treated patients, particularly in malnourishedpatients.
- Possible asymptomatic changes in haematological laboratory indices due to lack of available folatein folate deficient patients or to the elderly. Haemolysis in G-6-PD deficient patients.
- Should be given with caution to patients with severe allergy or bronchial asthma or in phenylketonuric patient sand in the treatment of streptococcal pharyngitis.

Pregnancy and Lactation: Not recommended in pregnant and breast-feeding women.

DOSAGE AND DIRECTIONS FOR USE:
Method of administration: Oral with some food or water.

Strength of Tablet	**80mg/400 mg**	**160mg/800 mg**
Standard Dose for Acute Infection & Prevention (See below)	2 tablets every 12 hours	1 tablet every 12 hours

Standard dosage recommendations for acute infections:
Adults and children over 12 years: 160mg trimethoprim/800mg sulfamethoxazole every 12hourly. Continued treatment until patient has been symptom free for 2 days; majority require treatment for at least 5 days. If no improvement, reassess after 7 days' therapy.
1 to 3 days' short-term therapy was effective for acute uncomplicated lower UTI.
The elderly: See Special Warnings and Precautions for Use.
Impaired hepatic function: No data for dosage in patients with impaired hepatic function.
Impaired renal function:

Creatinine Clearance (ml/min)	Recommended Dosage
>30	STANDARD DOSAGE
15 to 30	Half the STANDARD DOSAGE
<15	Not recommended