# Co-trimoxazole Tablets BP

**COMPOSITION:** **POM**

Each uncoated tablet contains:

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|---|---|
| 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 |