# CO - TRIMOXAZOLE

**Composition** : Active ingredients: trimethoprim ( TM ) & sulphamethoxazole ( SMZ ). The combination of the two active ingredients TM & SMZ has established itself under the name co-trimoxazole.

**Dosage form and amount of active ingredient per unit** :
scored beige - white tablets, 160 mg TM and 800 mgs SMZ .

**Indications and potential uses** : Infections due to co- trimoxazole - sensitive organisms, such as upper & lower respiratory tract infections :acute exbations of chronic bronchitis, bornchiectasis, pneumonia (including Penumocystis carinii pneumonia ), sinusits , otitis media .
Urogenital infections : acute and chronic cystitis, pyelonephritis , urethritis , prostatitis .
Gastrointestinal infections including typhoid and paratyphoid fever (including treatment of chronic carriers ), bacillary dysentery, and cholera (as an adjunct to fluid and electrolyte replacement ).
Other bacterial infections : acute and chronic osteomyelitis, acute brucellosis, nocardiosis, mycetoma (except when caused by true fungi ) , South American blastomycosis (Paracoccidioides brasiliensis )

**Dosage and administration** Normal dosage: Co-trimoxazole is administered at 12 hourly intervals. Adults & children over 12 years of age usually receive tablets or forte tablets , while children under 12 years of age are usually given syrup. In acute infections treatment with oral co-trimoxazole should continue for at least 5 days .
Co-trimoxazole is best taken after meals with plenty of fluid.
*Adults and children over 12 years:*

| | Tablets | | Forte filmcoated tablets | |
|---|---|---|---|---|
| | morning | evening | morning | evening |
| Standard dosage | 2 | 2 | 1 | 1 |
| min. dosage & dosage for long-term therapy (more than 5 days): | 1 | 1 | ½ | ½ |
| High dosage (for particularly severe cases ) | 3 | 3 | 1½ | 1½ |

**Contraindications** : Hypersensitivity to the active ingredients, to sulphonamides or trimethoprim or to any of the excipients. Co-trimoxazole is contraindicated in patients with marked liver parenchymal damage and also, unless TM & SMZ plasma concentrations can be determined repeatedly, in patients with severe renal impairment (creatinine clearance < 15 ml/min) Co-trimoxazole is likewise contraindicated in megaloblastic anemia due to folic acid deficiency. Co-trimoxazole should not be administered to premature infants or neonates during the first 6 weeks of life since this can lead to an increased risk for kernicterus.

**Warnings and Precautions:** Treatment should be discontinued immediately at the first appearance of skin rash or any other serious adverse reaction .In order to minimise the risk of adverse reactions , the duration of treatment with co - trimoxazole should be as short as possible particularly in elderly patients . Urine and renal function should be monitored regularly during long-terms treatment especially in patients with renal impairment.An adequate fluid intake and diuresis should be ensured during treatment in order to prevent crystalluria.Female patients should be advised to take additional contraceptive measures during co - trimoxazole treatment . Prolonged treatment with co-trimoxazole lead to overgrowth of non-sensitive organisms and fungi. Appropriate treatment should be initiatec immediately in the event of superinfection.Caution is indicated in patients with porphyria or thyroid dysfunction.In elderly patients or patients with renal impairment, hematological changes indicative of folic acid deficiency may occur. These can be reversed by folic acid therapy. Caution is indicated in patients with an additional risk factor for folic acid deficiency, e.g. Treatment with phenytoin or other folic acid antagonists, malnutrition. Trimethoprim has been found to have an adverse effect on phenylalanine metabolism. However, this has no relevance to patients with phenylketonuria who adhere to the indicated diet.

**Pregnancy** : Co-trimoxazole should bot be used during pregnancy unless clearly necessary. Co-trimoxazole appears to present no significant risk of teratogenicity in humans . Supplementary folic acid (5 mg/ day is recommended for pregnant women who require co-trimoxazole treatment.Co-trimoxazole should be avoided as far as possible during the last trimester, as it can increase the risk of kernicterus in the neonate.

**Lactation** :The amount of drug ingested by a breast-fed infant is extremely small, the benefit to the mother should be carefully weighed against the risk to the infant ( kernicterus, hypersensitivity ) **Ability to drive and use machines** Co-trimoxazole has no direct effects on the ability to drive vehicles or operate machines . Nevertheless, there is a possibility of adverse effects that impair these abilities, in some cases severely.

**Undesirable Effects** :Co-Trimoxazole is well tolerated at the recommended doses and any side effects that might occur will be mild and transient, these may include gastrointestinal disturbances (nausea, anorexia and vomiting ) skin rash and some hematological changes.

THIS IS A MEDICAMENT
- A medicament is a product which affects your health, & its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use & the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor

Medicine : Keep out of reach of children

- Store below 35°c

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