

CO-TRIMOXAZOLE

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about CO-TRIMOXAZOLE

Each tablet of CO-TRIMOXAZOLE contains 80 mg trimethoprim and 400 mg sulfamethoxazole.

Each 5 mL of CO-TRIMOXAZOLE suspension contain 40 mg trimethoprim and 200 mg sulfamethoxazole.

CO-TRIMOXAZOLE is a synthetic antibacterial combination of a sulfamide (sulfamethoxazole) and a diaminopyridine (trimethoprim). CO-TRIMOXAZOLE acts by blocking two consecutive steps in the biosynthesis of nucleic acids and proteins essential to many bacteria.

CO-TRIMOXAZOLE is indicated for the treatment of infections due to susceptible strains of organisms:

- Urinary tract infections in adults and pediatric patients
- Acute otitis media in pediatric patients
- Acute exacerbations of chronic bronchitis in adults
- Travelers' diarrhea in adults due to susceptible strains of E.coli
- Shigellosis in adults and pediatric patients
- Treatment and prevention of infections by *Pneumocystis carinii* in adults and pediatric patients

The way to take CO-TRIMOXAZOLE

Take CO-TRIMOXAZOLE as directed by your physician.

Dosage and duration of treatment are individualized on the basis of the condition under treatment. The dosage must not be changed without medical advice. It is preferable to administer the drug with meals. Dosage must be reduced in case of impaired renal function.

Adults:

The usual recommended dosage is 2 tablets or 20 mL of the suspension every 12 hours. In case of severe infections, dosage may be increased up to 6 tablets per day in 2 or 3 divided doses.

The usual recommended dosage for the treatment of acute uncomplicated cystitis in women less than 65 years old is 6 tablets in a single dose for 1 day.

Children 2 months of age and older:

The usual recommended dosage is 6-8 mg/kg/day trimethoprim and 30-40 mg/kg/day sulfamethoxazole in two divided doses.

The usual recommended dosage for the treatment of infections by *Pneumocystis carinii* in adults and children is 15 to 20 mg/kg/day trimethoprim and 75 to 100 mg/kg/day sulfamethoxazole in equally divided doses every 6 hours for 14 to 21 days.

Duration of treatment

Duration of treatment varies according to the disease and usually varies from 5 to 21 days.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- History of hypersensitivity to any of the components
- Patients with documented megaloblastic anemia due to folate deficiency
- In pregnant patients at term and in nursing mothers

- Pediatric patients less than 2 months of age

Precautions

- Discontinue treatment and consult your doctor at the first appearance of skin rash, diarrhea or any sign of adverse reaction.
- This drug must be used with caution in elderly patients, in case of impaired renal or hepatic function, possible folate deficiency, severe allergy, bronchial asthma or glucose-6-phosphate dehydrogenase-deficiency.
- Maintain an adequate fluid intake while undergoing therapy with this drug.
- Complete blood counts should be done frequently when receiving this medication.
- Inform your doctor before using this medication in case of pregnancy or lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

The concomitant use with methotrexate is contraindicated.

This drug must be used with caution with thiazide diuretics, oral anticoagulants, phenytoin, chlorpropamide, tolbutamide, sulfamide antidiabetics and drugs that may induce hyperkalemia (potassium salts, angiotensin-converting enzyme inhibitors, angiotensin II antagonists, NSAID, cyclosporine and tacrolimus).

Adverse reactions

The most reported adverse reactions include gastrointestinal disturbances (nausea, vomiting, anorexia) and allergic skin reactions such as rash and urticaria.

In rare cases this drug may cause hematologic disturbances, renal failure, hyperkalemia, hyponatremia, headache, nervousness, hypoglycemia, hepatitis, myalgia, cough, fatigue or insomnia.

Inform your doctor if any adverse effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

CO-TRIMOXAZOLE tablets, trimethoprim 80 mg and sulfamethoxazole 400 mg, pack of 20 tablets

CO-TRIMOXAZOLE suspension, trimethoprim 40 mg/ 5mL and sulfamethoxazole 200 mg/ 5 mL, bottle of 100 mL (with a dosing cup)

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