

CO-TRIMOXAZOLE TABLET

Sulphamethoxazole/Trimethoprim (400mg/80mg)

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What Co-Trimoxazole Tablets is used for

Co-Trimoxazole is a mixture of the sulphonamide, Sulphamethoxazole and Trimethoprim.

Co-Trimoxazole is widely used in variety of infections due to susceptible organisms, particularly those of the urinary, respiratory and gastrointestinal tracts.

Your doctor may have prescribed Co-Trimoxazole Tablet for another purpose. Ask your doctor if you have any questions why Co-Trimoxazole Tablet has been prescribed for you.

How Co-Trimoxazole Tablets works

Co-Trimoxazole belongs to a group of medicines called antibiotics. Co-Trimoxazole works by stopping the growth of the bacteria causing the infection.

Before you use Co-Trimoxazole Tablets

When you must not use it

- If you are allergic (hypersensitive) to trimethoprim or sulphonamide or any other ingredient of Co-Trimoxazole Tablets.
- If you have acute porphyria (a genetic metabolic disorder).
- If you have G6PD deficiency
- If you are going to deliver or a nursing mother.
- If it is for your child and they are less than 2 months of birth.

- If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Co-Trimoxazole Tablets.

Before you start to use it

You must tell your doctor or pharmacist if:

- you have allergies to any medicine which you have taken previously to treat your current condition.
- you are pregnant, trying to become pregnant or breast-feeding.
- you have kidney or liver disease.
- you are elderly.
- you have asthma.
- you have allergic disorder.
- you have acquired immune deficiency syndrome (AIDS)

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any of these medicines:

- Penicillin - medicines used to treat infection.
- Bone marrow depressants – medicines used to slow down the bone marrow function to produce white blood cells, red blood cells and plasma cells.
- Phenytoin, warfarin, methotrexate and hypoglycemic agents – medicines used to control seizures, medicines used to prevent heart attacks and blood clot, medicines used to treat cancer, and medicines used to treat diabetes.
- Zidovudine – medicines used to treat AIDS
- Cyclosporine – medicines used in organ transplantation to prevent rejection.
- Estrogen - containing oral contraceptives – medicines used for birth control
- Procainamide – medicines used to treat irregular heartbeats.
- Hepatotoxic agent and hemolytics – medicines that can cause damage to the liver and breakdown of red blood cells.

- Methenamine – medicines used to eliminates bacteria that cause urinary tract infections
- Dapsone – medicines used to treat leprosy (a contagious disease that affects the skin, mucous membranes, and nerves)
- Rifampicin – medicines used to treat bacterial infections.
- Diuretics – medicines used to promotes the production of urine.
- Phenylbutazone and sulfinpyrazone – medicines used for short-term treatment of pain and fever, and medicines used to treat gout.

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription.

How to use Co-Trimoxazole Tablets

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Take this medicine only by mouth.

How much to use

Adult

Usually 960mg (trimethoprim 160mg & sulphamethoxazole 800mg) twice daily. Severe infections: 2.88g daily in 2 divided dose.

Children

2-5 years: 240mg twice daily.
6-12 years: 480mg twice daily.

Co-trimoxazole should not be given to infants below 6 months because of the risk of kernicterus (brain damage caused by excessive jaundice) from the sulphonamide component.

Treatment of *Pneumocystis carinii* pneumonia: 120mg per kg body weight daily given in 3 to 4 divided doses for 14 to 21 days.

Patient with impaired renal function.

Your doctor might prescribes you a lower doses if you have kidney disease.

When to use it

Use as directed by your doctor or pharmacist. The tablet are taken orally, preferably 1 hour before food or 2 hours after meal.

How long to use it

Continue to use it for as long as your doctor recommends to use it.

If you forget to use it

- If you forget a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you take too much (Overdose)

Symptoms of sulphonamide poisoning are hematuria (presence of blood in urine). Other includes gastro-intestinal irritation, mental and visual disturbances and jaundice.

If you think you have taken an overdose of Co-trimoxazole Tablets, please tell your doctor who will then decide what action should be taken.

While you are using Co-Trimoxazole Tablets

Things you must do

Contact your doctor if your symptoms worsen or they do not improve.

If you do become pregnant whilst taking Co-trimoxazole Tablets, tell your doctor.

Things you must not do

Do not give Co-trimoxazole Tablets to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Co-trimoxazole Tablets for you and your condition.

Things to be careful of

- You must maintain adequate fluid intake because of the risk of crystalluria (crystals found in the urine) and administration of alkaline may be necessary if very large doses are used.
- Care must be taken for patients with liver or kidney function impairment. Dosage reduction may be necessary.
- Regular blood counts and urinalyses and kidney function tests should be

carried in patients receiving prolonged treatment.

- Discontinue treatment immediately if a skin rash appears or other adverse reactions occur.
- Caution is needed in patients with a history of allergy or asthma and in the elderly.
- Patients with acquired immune deficiency syndrome (AIDS) may be particularly prone to adverse reactions.

Fatalities associated with the administration of sulphonamide and trimethoprim, either alone or in combination, have occurred due to severe reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis (life-threatening skin condition) and other reactions. The drug should be discontinued at the first appearance of skin rash or any sign of adverse reaction.

Side Effects

Like all medicines, Co-trimoxazole Tablets can have side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Haematology: agranulocytosis (deficiency of white blood cells in the blood), aplastic anaemia (the body stops producing new blood cells), thrombocytopenia (deficiency of platelets), leucopenia (reduction in the number of white cells), hypoprothrombinemia (deficiency of blood clotting factor) and eosinophilia (increase in the number of eosinophils).
- Hypersensitivity: fever, rashes, photosensitivity reactions, exfoliative dermatitis (redness and peeling of the skin), toxic epidermal necrolysis (Lyell's Syndrome) (severe skin reaction) and erythema nodosum (red lumps below the skin surface). A severe, potentially fatal form of erythema multiforme (skin allergic reaction) associated with wide spread lesions of the skin and mucous membranes, termed Stevens-Johnson syndrome has occurred.

- Nephrotoxic: interstitial nephritis (swelling in between the kidney tubules) and tubular necrosis (damage to the kidney tubule cells) which may result in kidney failure. Lumbar pain, hematuria (presence of blood in urine), oliguria (low output of urine) and anuria (nonpassage of urine) may also occur due to crystallisation in the urine of sulphamethoxazole or its less soluble acetylated metabolite.
- Neurology: inflammation of the tissue that covers the brain, loss of control of bodily movements, benign intracranial hypertension (increased pressure around the brains), convulsions, dizziness, drowsiness, fatigue, headache, insomnia, mental depression, damage to the optic nerve, sensation that the environment around is moving or spinning.
- Gastro-intestinal: Nausea, vomiting, anorexia, diarrhoea. Pseudomembranous colitis (infection of the large intestine) may occur.
- Others: syndrome resembling serum sickness, liver necrosis, hepatomegaly (enlargement of the liver) and jaundice, myocarditis (inflammation of the heart muscle), pancreatitis, pulmonary eosinophilia (accumulation of white blood cells in the lungs) and fibrosing alveolitis (thickening of the walls of the alveoli in the lung), vasculitis including polyarthritis nodosa (swollen of arteries), hypoglycemia (low blood sugar level) and hypothyroidism (low level of thyroid hormone). Anaphylaxis (acute allergic reaction) has been reported very rarely.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Consult your doctor or pharmacist if you are in doubt or for any further information.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my

(Public→Reporting Medicinal Problems/ Side Effects/ AEFI/ Vaccine Safety)

Date of Revision

11/05/2017

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Storage and Disposal of Co-Trimoxazole Tablets

Storage

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Co-trimoxazole Tablets should be stored at room temperature (27-30°C). Protect from heat and moisture.

Keep out of the reach and sight of children.

Disposal

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What Co-Trimoxazole Tablets looks like

The tablets are white, round, scored of diameter 12.5mm flat with 'MPI' marking.

They are supplied in 100 x 10's blisterpack.

Ingredients

- Active ingredient(s)
Each tablet contains 400mg Sulphamethoxazole and 80mg Trimethoprim.
- Inactive ingredients
The other ingredients are gelatin, potato starch, dried potato starch and talc.

MAL Number

MAL19900415AZ

Manufacturer and Product Registration Holder

Malaysian Pharmaceutical Industries Sdn. Bhd.

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