

MILAN LABORATORIES (INDIA) PVT. LTD.

BETRIM 480 (Co-trimoxazole Tablets BP 480 mg)

BETRIM FORTE (Co-trimoxazole Tablets BP 960 mg)



PATIENT INFORMATION LEAFLET (PIL)

BETRIM 480 (Co-trimoxazole Tablets BP 480 mg)

BETRIM FORTE (Co-trimoxazole Tablets BP 960 mg)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

- a) What Co-Trimoxazole is and what it is used for
- b) Before you take Co-Trimoxazole
- c) How to take Co-Trimoxazole
- d) Possible side effects
- e) How to store Co-Trimoxazole
- f) Further information

a) What Co-Trimoxazole is and what it is used for

Co-Trimoxazole are made up of two different medicines called sulfamethoxazole and trimethoprim. These medicines are sometimes given the combined name Co-trimoxazole. Both belong to a group of medicines called antibiotics. They are used to treat infections caused by bacteria. Like all antibiotics, Co-Trimoxazole only works against some types of bacteria. This means that it is only suitable for treating some types of infections. Co-Trimoxazole can be used to treat or prevent:

- lung infections (pneumonia or PCP) caused by a bacteria called *Pneumocystis jiroveci*
- infections caused by a bacteria called *Toxoplasma* (toxoplasmosis).

Co-Trimoxazole can also be used to treat:

- Urinary tract infections

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- lung infections such as bronchitis
- ear infections such as otitis media
- an infection called nocardiosis, it can affect the lungs, skin and brain.

b) Before you take Co-Trimoxazole

Do not take Co-Trimoxazole:

- if you are allergic to sulfamethoxazole, trimethoprim or any of the other ingredients.
- if you have liver or kidney problems.
- if you have a history of blood disorders which increases risk of bleeding or bruising (thrombocytopenia)
- if you have a rare blood disorder called porphyria
- if you are pregnant or planning to become pregnant

Co-trimoxazole should not be given to newborn babies under 6 weeks old except for *Pneumocystis jiroveci* (*P.carinii*) infection.

Take special care with Co-trimoxazole if you

- have glucose 6 phosphate dehydrogenase deficiency it may lead to haemolysis (a blood disorder)
- have Group A beta-haemolytic streptococci (abacterial infection)
- have malnutrition

Talk to your doctor before taking Co-Trimoxazole if:

- you have severe allergies or asthma.
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Co-trimoxazole appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
- additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).
- these potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

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- the highest risk for occurrence of serious skin reactions is within the first weeks of treatment.
- if you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Co-trimoxazole you must not be re-started on Co-trimoxazole at any time.
- if you develop a rash or these skin symptoms, stop taking Co-trimoxazole, seek urgent advice from a doctor and tell him that you are taking this medicine.
- you have been told that you have a rare blood problem called porphyria, which can affect your skin or nervous system.
- you don't have enough folic acid (a vitamin) in your body - which can make your skin pale and make you feel tired, weak and breathless. This is known as anaemia.
- you have ever had jaundice which can cause yellowing of your skin or the whites of your eyes.
- you have a problem with your metabolism called phenylketonuria and are not on a special diet to help your condition.
- you are elderly.
- you are underweight or malnourished.
- you have been told by your doctor that you have a lot of potassium in your blood. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-trimoxazole.

Other medicines and Co-trimoxazole:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which may interact with or be affected by Co-trimoxazole:

- Diuretics (water tablets), such as bendroflumethiazide
- Pyrimethamine, used to treat and prevent malaria, and to treat diarrhoea
- Ciclosporin, used after transplant operations or for your immune system
- Medicines used to thin the blood such as warfarin
- Phenytoin, used to treat epilepsy (fits)
- Medicines for diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas)

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- Medicines to treat problems with the way your heart beats such as digoxin or Procainamide
- Amantadine, used to treat Parkinson's disease, multiple sclerosis, 'flu or shingles
- Medicines to treat HIV (Human Immunodeficiency Virus), called zidovudine or Lamivudine
- Medicines that can increase the amount of potassium in your blood, such as diuretics (water tablets, which help increase the amount of urine you produce), steroids (like prednisolone) and digoxin
- Methotrexate, a medicine used to treat cancer or for your immune system.
- ACE inhibitors (to treat high blood pressure e.g. captopril, lisinopril)
- Anaesthetics such as prilocaine
- Amiodorone, dofetilide (to treat some heart conditions)
- Antibiotics such as rifampicin, dapsone, methenamine

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

Taking Co-trimoxazole with food and drink

You should take Co-trimoxazole with some food or drink. This will stop you feeling sick (nausea) or having diarrhoea. Although it is better to take it with food, you can still take it on an empty stomach.

Drink plenty of fluid such as water while you are taking Co-trimoxazole.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Co-trimoxazole may make you feel drowsy or dizzy or cause hallucinations, ringing in the ears or sleeplessness. Make sure you are not affected before you drive or operate machinery.

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Always take Co-trimoxazole exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

- These tablets are to be taken orally.
- The tablets should be taken with some food or drink.
- Treatment should be continued until you have been free from symptoms for 2 days. It is likely you will require treatment for at least 5 days. If there is no improvement after 7 days of treatment, you should be reassessed by your doctor.

Adults

For Co-trimoxazole Tablets BP 480mg:

- The standard dose for infections is 2 tablets every 12 hours.
- For prevention of infections, ONE of the following doses may be used:
 - 2 tablets (160mg trimethoprim/800mg sulfamethoxazole) daily for 7 days
 - 2 tablets (160mg trimethoprim/800mg sulfamethoxazole) 3 times a week on alternate days
 - 2 tablets (160mg trimethoprim/800mg sulfamethoxazole) twice daily, 3 times a week on alternate days

For Co-trimoxazole Tablets BP 960mg:

- The standard dose for infections is 1 tablet every 12 hours.
- For prevention of infections, ONE of the following doses may be used:
 - 1 tablet (160mg trimethoprim/800mg sulfamethoxazole) daily for 7 days
 - 1 tablet (160mg trimethoprim/800mg sulfamethoxazole) 3 times a week on alternate days
 - 1 tablet (160mg trimethoprim/800mg sulfamethoxazole) twice daily, 3 times a week on alternate days

The total daily dose should not exceed 320mg trimethoprim/1600mg sulfamethoxazole.

Use in children

Co-trimoxazole Tablets are not recommended for use in children under 12 years of age.

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The standard dosage is equivalent to approximately 6mg of trimethoprim and 30mg of sulfamethoxazole per kg of body weight per 24 hours, given in 2 equally divided doses.

The schedules for children according to the child's age and body weight are provided in the table below:

Age	Recommended Dose (Co-trimoxazole Tablets 480mg)	Recommended Dose (Co-trimoxazole Tablets 960mg)
Children aged 12-18 years	Two tablets every 12 hours	One tablet every 12 hours
Body Weight	Recommended Dose for 80/400mg	Recommended Dose for 160/800mg
Body weight of 27kg or above	One tablet every 12 hours	NOT RECOMMENDED
Body weight of 53kg or above	Two tablets every 12 hours	One tablet every 12 hours

If you take more Co-trimoxazole than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department immediately for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of an overdose may include: feeling (nausea) or being (vomiting) sick, difficulty urinating, swelling of the face, weakness, dizziness and confusion. Symptoms of bone marrow depression (condition of the bone marrow in which it is unable to produce normal amounts of red blood cells, white blood cells, and platelets leaving the immune system in a weakened state and vulnerable to infection) may also develop.

If you forget to take Co-trimoxazole

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do not take a double dose to make up for a forgotten dose.

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If you stop taking Co-trimoxazole

Do not stop taking Co-trimoxazole because you feel better. Take the Co-trimoxazole for as long as your doctor has told you or your problem may come back.

d) Possible side effects

Like all medicines, Co-trimoxazole can cause side effects, although not everybody gets them. Stop taking Co-trimoxazole and tell your doctor immediately if you have an allergic reaction. Chances of an allergic reaction is very rare (fewer than 1 in 10,000 people are affected), signs of an allergic reaction include

Allergic reactions:

- Difficulty in breathing
- Fainting
- Swelling of the face, throat or tongue which may be red and painful and/or cause difficulty in swallowing
- Chest pain
- Red patches on the skin

Very Common (more than 1 in 10 people)

- High levels of potassium in your blood, which can cause abnormal heart beats (palpitations).

Common (less than 1 in 10 people)

- An infection called thrush or candidiasis which can affect your mouth or vagina. It is caused by a fungus
- Headache
- Feeling sick (nausea)
- Diarrhoea
- Skin rashes

Uncommon (less than 1 in 100)

- Being sick (vomiting)

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Very rare (less than 1 in 10,000 people)

- Fever (high temperature) or frequent infections
- Sudden wheeziness or difficulty breathing
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported.
- Mouth ulcers, cold sores and ulcers or soreness of your tongue
- Skin lumps or hives (raised, red or white, itchy patches of skin)
- Blisters on your skin or inside your mouth, nose, vagina or bottom
- Inflammation of the eye which causes pain and redness
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- Low levels of sodium in your blood
- Changes in blood tests
- Feeling weak, tired or listless, pale skin (anaemia)
- Heart problems
- Jaundice (the skin and the whites of your eyes turn yellow). This can occur at the same time as unexpected bleeding or bruising
- Pains in your stomach, which can occur with blood in your faeces (poo)
- Pains in your chest, muscles or joints and muscle weakness
- Arthritis
- Problems with your urine. Difficulty passing urine. Passing more or less urine than usual. Blood or cloudiness in your urine.
- Kidney problems
- Sudden headache or stiffness of your neck, accompanied by fever (high temperature)
- Problems controlling your movements
- Fits (convulsions or seizures)
- Feeling unsteady or giddy
- Ringing or other unusual sounds in your ears
- Tingling or numbness in your hands and feet
- Seeing strange or unusual sights (hallucinations)
- Depression

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- Muscle pain and/or muscle weakness in HIV patients.

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.

e) How to store Co-trimoxazole

Keep out of the reach and sight of children.

Do not store above 30°C, Protect from light.

Store in the original package in order to protect from heat, light and moisture.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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

f) Further information

What Co-trimoxazole Tablets contains

- The active substances are of Trimethoprim and Sulfamethoxazole.

Co-trimoxazole Tablets BP 480mg:

Each tablet contains: 80mg of Trimethoprim and 400mg of Sulfamethoxazole.

Co-trimoxazole Tablets BP 960mg:

Each tablet contains: 160mg of Trimethoprim and 800mg of Sulfamethoxazole.

- The other ingredients are:

Maize starch, Microcrystalline cellulose, Sodium Starch Glycolate, Gelatin, Methyl Paraben, Propyl Paraben, Purified talc, Starch Lauryl Sulfate & Magnesium Stearate.

What Co-trimoxazole Tablets looks like and contents of the pack

Co-trimoxazole Tablets BP 480mg: White colored circular, uncoated tablet having “COTRIM/480” engraved on one side and plain on other side of each tablet.

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Co-trimoxazole Tablets BP 960mg: White, uncoated caplet with inscription M/L on one side and plain on other side.

PRESENTATION:

Co-trimoxazole Tablets BP 480mg & Co-trimoxazole Tablets BP 960mg are available in Alu-PVC Blister pack of 10 x10 Tablets

Marketing Authorisation Holder

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