

**1.4 Product information****1.4.3 Patient Information Leaflet(PIL)**

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE BECAUSE IT CONTAINS

IMPORTANT INFORMATION FOR YOU.

- KEEP THIS LEAFLET. YOU MAY NEED TO READ IT AGAIN.
- IF YOU HAVE ANY FURTHER QUESTIONS, ASK YOUR DOCTOR OR PHARMACIST.
- THIS MEDICINE HAS BEEN PRESCRIBED FOR YOU ONLY. DO NOT PASS IT ON TO OTHERS. IT MAY HARM THEM, EVEN IF THEIR SIGNS OF ILLNESS ARE THE SAME AS YOURS.
- IF YOU GET ANY SIDE EFFECTS, TALK TO YOUR DOCTOR OR PHARMACIST. THIS INCLUDES ANY POSSIBLE SIDE EFFECTS NOT LISTED IN THIS LEAFLET.

What is in this leaflet

1. What Co-trimoxazole Tablet BP 480 mg are and what they are used for
2. What you need to know before you take Co-trimoxazole Tablet BP 480 mg
3. How to take Co-trimoxazole Tablet BP 480 mg
4. Possible side effects.
5. How to store Co-trimoxazole Tablet BP 480 mg
6. Further Information.

1. What Co-trimoxazole Tablet BP 480 mg are and what they are used for

Co-Trimoxazole contains two active ingredients, trimethoprim and sulfamethoxazole, both antibiotics,

used to treat infections caused by certain bacteria.

Co-Trimoxazole can be used to treat or prevent:

- Lung infections (pneumonia) caused by the bacteria pneumocytosis jiroveci
- Infections caused by the bacteria toxoplasma (toxoplasmosis)

Co-Trimoxazole can also be used to treat:

- Urinary tract infections
- Respiratory tract infections such as bronchitis
- Short-lived ear infections (acute otitis media)
- A rare infection of the lungs, brain or skin (nocardiosis)

Co-Trimoxazole is indicated for the treatment of adults (over 18 years of age) and children from 12-18 years of age.

2. What you need to know before you take Co-trimoxazole Tablet BP 480 mg**Do not take Co-trimoxazole Tablet BP 480 mg :**

- You are allergic to sulfamethoxazole, trimethoprim or any of the other ingredients of this medicine (listed in section 6)
- You have severe liver or kidney problems
- Co-Trimoxazole should not be given to infants during the first 6 weeks of life



- You have a history of blood disorders which increases risk of bleeding or bruising (thrombocytopenia)
- You have a rare blood disorder called porphyria (see “Warnings and precautions” section)

Warnings and Precautions

Talk to your doctor before taking Co-Trimoxazole if:

You develop a severe skin rash/reaction (e.g. Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, Acute Generalised Exanthematous Pustulosis) or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or a blood disorder as Co-Trimoxazole should be discontinued (see section 4 “Possible side effects”)

- You develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately
- You have a history of allergies or asthma
- You have kidney or liver problems
- You do not have enough folic acid (vitamin) in your body
- You are known to have a glucose-6-phosphate dehydrogenase deficiency. It is a hereditary condition which causes the red blood cells to break down. when the body is exposed to infections or certain medicines
- You have a metabolism disorder called phenylketonuria and you are not on a special diet to control your condition
- You are elderly, as you are more prone to side effects, especially if you have kidney and/or liver problems and/or are taking other medicines
- You have a bacterial infection known as Group A beta-haemolytic streptococci
- Concomitant administration of Co-Trimoxazole with certain medicines (see “Other medicines and Co-Trimoxazole” section) may lead to severe hyperkalaemia (increased potassium blood level). The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, feeling sick (nausea), dizziness or headache
- You are known to be at risk of having hyponatraemia, as your blood sodium (salt) levels should be closely monitored
- You are suffering from malnutrition
- You are known or suspected to be at risk of porphyria (a group of rare inherited or acquired disorders where there is a problem with the production of haem (used to make haemoglobin in red blood cells) within the body) (See “Do not take” section)
- Your treatment with Co-Trimoxazole is prolonged, especially if you have low folate levels or you are elderly as it is recommended that complete blood counts be performed at monthly intervals.

Haemophagocytic lymphohistiocytosis

There have been very rare reports about excessive immune reactions due to a dysregulated activation of white blood cells resulting in inflammations (haemophagocytic lymphohistiocytosis), which can be life-threatening if not diagnosed and treated early. If you experience multiple symptoms such as fever, swollen glands, feeling weak, lightheaded, shortness of breath, bruising, or skin rash simultaneously or with a slight delay, contact your doctor immediately.

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:

- Warfarin, used to prevent the blood from clotting (anticoagulants)
- Phenytoin, used to treat epilepsy
- Digoxin and procainamide, used to treat an irregular heartbeat
- Amantadine, used to treat some viral infections and also Parkinson's disease
- Medicines for diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylurea hypoglycaemic medicines) and repaglinide
- Folic acid
- Contraceptives
- Methotrexate and azathioprine, used to treat immune disorders
- Cyclosporin, used after transplant operations or for your immune system
- Pyrimethamine, used to prevent malaria
- ACE inhibitors, used to treat high blood pressure, such as captopril or lisinopril
- Rifampicin, used to treat bacterial infections (antibiotics)
- Lamivudine and zidovudine, used to treat viral infections
- Spironolactone (potassium-sparing diuretic), diuretics (water tablets), which help increase the amount of urine produced. In particular, thiazides, such as bendroflumethiazide

Laboratory tests

If you need to have laboratory tests, let your doctor know that you are taking Co-Trimoxazole as it may affect the results.

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.

Pregnancy

- Co-Trimoxazole should not be used during pregnancy particularly in the first trimester (first 3 months of pregnancy), unless necessary.
- Folate supplements such as folic acid should be considered if Co-Trimoxazole is used in pregnancy.

Breast-feeding:

- Both sulfamethoxazole and trimethoprim (the active ingredients in Co-Trimoxazole) are passed into the breast milk.
- Co-Trimoxazole should be avoided where the breast-feeding mother or infant has, or is at risk of developing a condition in which there is too much bilirubin in the blood (hyperbilirubinaemia), particularly in infants younger than eight weeks old as they are more at risk of developing this condition.

Driving and using machines

Effects on the ability to drive and operate machinery in patients taking Co-Trimoxazole have not been studied. If you experience any side effects when taking this medicine, you should not



drive or operate machinery.

Co-Trimoxazole contains Sodium

This medicine contains less than 1 mmol sodium (23mg) per 80/400mg /160/800mg tablet, that is to say essentially ‘sodium-free’.

3. How to take Co-Trimoxazole

Always take Co-Trimoxazole exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- These tablets are to be taken orally
- The tablets should be taken with some food or drink
- The score line on the tablet is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.
- 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.

AdultsCo-Trimoxazole 160/800mg Tablets

- The standard dose for infections is 1 tablet every 12 hours
- For prevention of infections, ONE of the following doses may be used:
 - o 1 tablet (160mg trimethoprim/800mg sulfamethoxazole) daily for 7 days
 - o 1 tablet (160mg trimethoprim/800mg sulfamethoxazole) 3 times a week on alternate days
 - o 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 80/400mg and Co-Trimoxazole 160/800mg are not recommended for use in children under 12 years of age.

Children aged 12 – 18 years

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 for 80/400mg
Children aged 12-18 years	One tablet every 12 hours
Body Weight	Recommended Dose for 80/400mg
Body weight of 27kg or above	NOT RECOMMENDED
Body weight of 53kg or above	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, 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.

If you stop taking Co-Trimoxazole

It is important that you keep taking this medicine for as long as your doctor has told you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness (anaphylaxis)
- Small raised bumps on the skin that fill with fluid or pus caused by a hypersensitivity (allergy) to medicine (Acute Generalised Exanthematous Pustulosis)
- Frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)
- A type of delayed allergic reaction (serum sickness)
- Inflammation of the heart muscle caused by allergic reaction to medication (allergic myocarditis)
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Serious inflammation of the linings of the brain (aseptic meningitis)
- Peeling of the skin over large areas of the body (exfoliative dermatitis)
- A type of allergic reaction to a medicine causing skin lesions (fixed drug eruption)
- Fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme)
- Severe blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis)
- Fever, general ill feeling, swollen/enlarged lymph nodes and skin eruption (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS])
- Build-up of bile acids in the bloodstream causing yellowing of the skin or whites of the eyes (cholestatic jaundice)
- Liver failure (hepatic necrosis)

Very Common side effects (may affect more than 1 in 10 people)

- Abnormally high levels of potassium in blood (hyperkalaemia)

Common side effects (may affect up to 1 in 10 people)

- Increase in fungal infections



- Headache
- Nausea (feeling sick)
- Diarrhoea
- Skin rashes

Uncommon side effects (may affect up to 1 in 100 people)

- Vomiting (being sick)

Very rare side effects (may affect less than 1 in 10,000 people)

Inflammation of the colon that occurs in some people who have taken antibiotics (pseudomembranous colitis)

- A reduction in white blood cells (leucopenia, neutropenia) which increases risk of infections (agranulocytosis)
- A reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- A blood disorder caused by incomplete formation of the red blood cells (megaloblastic anaemia)
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia)
- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia)
- A blood disorder in which an abnormal amount of methemoglobin (a form of haemoglobin) is produced (methaemoglobinaemia)
- Skin rash caused by small blood vessels bleeding into the skin (purpura)
- Disintegration of red blood cells (haemolysis) in certain susceptible patients
- Inflammation of the blood vessels (allergic vasculitis/Henoch-Schoenlein purpura)
- Inflammation of the walls of the arteries (periarteritis nodosa)
- Long-term inflammation of skin &/or intestines (Systemic Lupus Erythematosus)
- Fever
- Increased level of liver enzymes and bilirubin (detected by blood test)
- Abnormally low levels of salt (sodium) in blood (hyponatraemia)
- Condition in which damaged skeletal muscle tissue breaks down (rhabdomyolysis)
- Low blood sugar levels (hypoglycaemia)
- Loss of appetite
- Increased level of acid in the blood (metabolic acidosis)
- Depression
- Seeing or hearing things that are not real (hallucinations)
- Fits (convulsions)
- Disorders of the nervous system e.g. pain, numbness and tingling affecting hands &/or feet (peripheral neuropathy)
- Lack of voluntary co-ordination of muscle movements [unsteadiness or clumsiness] (ataxia)
- Dizziness
- A sensation of whirling and loss of balance, feeling dizzy or giddy (vertigo)
- Ringing in the ears (tinnitus)
- Inflammation of the eye causing redness & pain (uveitis)
- Cough
- Shortness of breath or difficulty in breathing (dyspnoea, pulmonary infiltrates)

(Co-trimoxazole Tablet BP 480 mg)

- Inflammation of the tongue (glossitis) or mouth (stomatitis)
- Inflammation of the pancreas (pancreatitis)
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Pain or swelling in the joints (arthralgia)
- Muscle pain (myalgia)
- Impaired kidney function, kidney failure, inflammation of the kidney (interstitial nephritis)

Other side effects (frequency not known)

- Mental illness (psychotic disorders)
- Plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweet's Syndrome)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

5. How to store Co-Trimoxazole

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Co-Trimoxazole 80/400 Tablets are available in 10 x10 Alu PVC pack

6. Further information**What Co-Trimoxazole Tablets contain:**

- Each Co-Trimoxazole 80/400mg tablet contains 80mg of Trimethoprim BP and 400mg of sulfamethoxazole BP

The other ingredients are:

Ingredients (Core)	
Maize Starch	BP
Povidone (PVP K30)	BP
Maize Starch	BP
Methyl Hydroxy benzoate	BP
Propyl Hydroxy benzoate	BP
Purified Water*	BP
Sodium Starch Glycollate	USP/NF
Magnesium Stearate	BP

What Co-Trimoxazole Tablets look like and the contents of the pack:

- Co-Trimoxazole 80/400mg are White to off white flat circular bevel edged uncoated tablets with a break line on one side plain on other side.

The marketing authorisation holder and manufacturer

Bal Pharma Limited
21 & 22, Bommasandra industrial Area,

BALTRIM

(Co-trimoxazole Tablet BP 480 mg)



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