

Package leaflet: Information for the user

Co-Trimoxazole Tablets

Trimethoprim 80mg

Sulfamethaxazole 400mg

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Co-Trimoxazole Tablets is and what it is used for
2. What you need to know before you take Co-Trimoxazole Tablets
3. How to take Co-Trimoxazole Tablets
4. Possible side effects
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6. Contents of the pack and other information

1. What Co-Trimoxazole Tablets is and what it is used for

Co-trimoxazole 80 mg/400 mg Tablets (called 'Co-trimoxazole tablets' in this leaflet) are made up of two different medicines called sulfamethoxazole and trimethoprim. 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 tablets are used for adults and children over 12 years.

Co-trimoxazole tablets 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 tablets can be used to treat:

- bladder or urinary tract infections (water infections)
- lung infections such as bronchitis
- ear infections such as otitis media
- an infection called nocardiosis, it can affect the lungs, skin and brain.

2. What you need to know before you take Co-Trimoxazole Tablets

Do not take Co-Trimoxazole Tablets

- you are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or Co-trimoxazole or any of the other ingredients of Co-trimoxazole tablets (see section 6)
- you are allergic to sulfonamide medicines. Examples include sulfonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – a water tablet)
- you have liver or kidney problems
- you have ever had a problem with your blood causing bruises or bleeding (thrombocytopenia)
- you have been told that you have a rare blood problem called porphyria, which can affect your skin or nervous system
- Co-trimoxazole should not be given to infants during the first 6 weeks of life.

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

3. How to take Co-trimoxazole tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults (>18 years old): STANDARD DOSAGE

Age	Tablets
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>18 years old	2 Tablets every 12 hours
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<p>➤ 12 years 480mg twice daily (Sulphamethoxazole 400mg & Trimethoprim 80mg) Or as directed by the physician.</p>
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- Co-trimoxazole should be taken for at least five days.
- Make sure that you finish the course of Co-trimoxazole which your doctor has prescribed.

Special Dose

The dose of Co-trimoxazole tablets and how long you need to take it depends on the infection you have and how bad it is. Your doctor may prescribe you a different dose or length of course of Co-trimoxazole to:

- treat urinary tract (water) infections
- treat and prevent lung infections caused by the bacteria *Pneumocystis jiroveci*
- treat infections caused by the bacteria *Toxoplasma* (toxoplasmosis) or *Nocardia* (nocardiosis).

If you have kidney problems your doctor may:

- prescribe a lower dose of Co-trimoxazole tablets
- take blood to test whether the medicine is working properly.

If you take Co-trimoxazole tablets for a long time your doctor may:

- take blood to test whether the medicine is working properly
- prescribe folic acid (a vitamin) for you to take at the same time as Co-trimoxazole tablets.

If you take more Co-trimoxazole tablets than you should

If you take more Co-trimoxazole tablets than you should, talk to your doctor or go to a hospital straight away. Take the medicine pack with you. If you have taken too many Co-trimoxazole tablets you may:

- feel or be sick
- feel dizzy or confused.

If you forget to take Co-trimoxazole tablets

If you forget to take a dose, take it as soon as you remember it. Do not take a double dose to make up for the forgotten dose.

4. Possible side effects

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

Stop taking Co-trimoxazole tablets 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:

- Difficulty in breathing
- Fainting
- Swelling of face
- Swelling of mouth, tongue or throat 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)

- Excessive potassium in the blood (may occur as muscle cramps or pain, irregular heartbeats, unusual tiredness or weakness).

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.
- 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 have a kidney disease
- 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 tablets.

Skin reactions - if you develop a rash or any of the following symptoms, seek immediate advice from a doctor and tell them that you are taking this medicine:

- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS)) 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. If you have developed Stevens-Johnson syndrome, toxic epidermal necrolysis or DRESS with the use of Co-trimoxazole tablets you must not be re-started on Co-trimoxazole tablets at any time.
- 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
- the highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

Other medicines and Co-trimoxazole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This includes herbal medicines. This is because Co-trimoxazole tablets can affect the way some medicines work. Also some other medicines can affect the way Co-trimoxazole tablets work.

- Diuretics (water tablets), which help increase the amount of urine you produce
- Pyrimethamine, used to treat and prevent malaria, and to treat diarrhoea
- Ciclosporin, used after organ transplant surgeries
- Blood thinners such as warfarin
- Phenytoin, used to treat epilepsy (fits)
- Medicines used to treat diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas) and repaglinide
- Rifampicin, an antibiotic

- Medicines to treat problems with the way your heartbeats 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, such as spironolactone), steroids (like prednisolone), digoxin
- Methotrexate, a medicine used to treat certain cancers or certain diseases affecting your immune system
- Folinic acid
- Contraceptive medicines.

Co-trimoxazole tablets with food and drink

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

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to get pregnant, or breast-feeding.

Driving and using machines

When driving vehicles or using machines, it should be taken into account that occasionally dizziness or fits may occur.

5. How to store Co-Trimoxazole Tablets

Store in a cool and dry place, not above 30°C. Keep out of the reach of children.

Do not use Co-trimoxazole tablets after the expiry date stated on the label/ carton/bottle. The expiry date refers to the last day of that month.

Ask your pharmacist how to dispose of medicines no longer required.

6. Further Information

What Co-trimoxazole tablets contain,

The active substances (the ingredients that make the tablets work) are 80mg of trimethoprim and 400mg of sulfamethoxazole.

Maize starch, Gelatin, Methyl paraben, Propyl paraben, Talc, Magnesium stearate, Cross carmellose sodium, Sodium starch glycolate.

What Co-trimoxazole tablets look like and contents of the pack

A white biconvex circular uncoated tablet with “CO-TRI /480” on one face and M/G on the other side.

Co-trimoxazole Tablets BP Skillet contains 50 blister strips of 10 tablets each with a packing insert.

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This leaflet was last approved on :