

Package leaflet: Information for the user

Co-Trimoxazole Tablets BP (400/80)

Sulfamethoxazole, Trimethoprim

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. See section 4.

What is in this leaflet

1. What Co-Trimoxazole Tablets are and what they are used for
2. What you need to know before you take Co-Trimoxazole Tablets
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1. What Co-Trimoxazole Tablets are and what they are used for

Co-Trimoxazole Tablets contain sulfamethoxazole and trimethoprim. These are antibiotics. Together they work by stopping the growth of bacteria which cause infections such as:

- pneumonia, bronchitis, chest infections
- ear infections
- brain infections
- urinary tract infections
- skin infections

Co-Trimoxazole Tablets are used for adults and children from 6 years of age.

Co-Trimoxazole Tablets are not recommended for children under 6 years of age.

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

Do not take Co-Trimoxazole Tablets:

- if you are allergic to sulfamethoxazole, trimethoprim or any other sulfonamide, or to any of the other ingredients of this medicine (listed in section 6)
- if you have liver disease
- if you have a blood disorder
- if you have severe kidney problems.

Co-trimoxazole should not be given to infants during the first 6 weeks of life.

If any of the above apply to you, speak to your doctor or pharmacist.

Take special care with Co-Trimoxazole Tablets:

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of Co-Trimoxazole Tablets.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen

eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.

- DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

The occurrence, at the beginning of the treatment, of a red, scaly widespread rash with bumps under the skin and blisters and blister accompanied by fever may be a symptom of acute generalised exanthematous pustulosis (AGEP).

The highest risk for occurrence of serious skin reactions is within the first weeks of treatment. If you develop a serious rash or another of these skin symptoms, stop taking Co-Trimoxazole Tablets and contact your doctor or seek medical attention immediately.

Warnings and precautions

Talk to your doctor before taking Co-Trimoxazole Tablets:

- if you have lung problems (e.g. asthma)
- if you have severe allergies (e.g. hayfever)
- if you are over 65 years of age, as the elderly may get more side effects
- if you have a folic acid deficiency
- if you could be suffering from malnutrition (e.g. due to dieting or bowel problems)
- if you have glucose-6-phosphate dehydrogenase (G6PD) deficiency
- if you suffer from phenylketonuria (an enzyme deficiency) and are not on a special diet
- if you have porphyria (a metabolism disorder which causes abdominal pains and mental disorder)
- if you have HIV (Human Immunodeficiency Virus)
- if you have a bacterial throat infection called streptococcal pharyngitis
- if you have ever had high blood potassium levels
- if you are taking pyrimethamine, a medicine for malaria
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Co-Trimoxazole or other trimethoprim-sulfamethoxazole containing drugs.

Concomitant administration of Co-Trimoxazole Tablets with certain medicines, potassium supplements and food rich in potassium may lead to severe hyperkalaemia (increased potassium blood level). The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.

If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately.

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 Tablets

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

Some medicines may be affected by Co-Trimoxazole Tablets or they may affect how well Co-Trimoxazole Tablets will work. Tell your doctor or pharmacist if you are taking:

- diuretics (water tablets)
- digoxin, used to treat heart conditions

- medicines likely to increase the amount of potassium in your blood (e.g. ACE-inhibitors and spironolactone)
- medicines for diabetes
- medicines that thin the blood e.g. warfarin
- methotrexate, a medicine used to treat arthritis or cancer
- ciclosporin, a medicine used to suppress the immune system
- phenytoin, a medicine used in the treatment of epilepsy
- HIV medicines, such as zidovudine and lamivudine
- procainamide, a medicine used to treat certain heart conditions
- amantadine, a medicine used to treat the flu and also Parkinson's Disease
- pyrimethamine, a medicine for malaria.

Pregnancy and breast-feeding

DO NOT take Co-Trimoxazole Tablets if you are pregnant, especially in early or late pregnancy, or while breast-feeding unless advised by your doctor.

If you are 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 Tablets may cause dizziness, head-spins and lack of co-ordination. If this occurs do not drive, use machinery, or perform any tasks that may require you to be alert until the symptoms abate.

Co-Trimoxazole Tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Co-Trimoxazole Tablets

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

- Swallow the tablets with plenty of water, **after a meal** to prevent upset stomach. It is important to drink plenty of fluids while you are taking Co-Trimoxazole Tablets.

The recommended doses to treat infections

Adults: the usual dose is two tablets twice a day (every 12 hours).

Children 6 to 12 years: one tablet twice a day (every 12 hours).

Children under 6 years: this medicine is NOT suitable for children under 6 years.

Treatment will normally be given for 1-5 days. If no improvement is seen after 7 days the doctor will reassess you.

The recommended doses to treat Pneumocystis infections jirovecii lung infection (PCP)

Your doctor may prescribe higher doses than usual for more than 7 days.

The recommended doses to prevent Pneumocystis infections

Adults:

- two tablets once a day on each day of the week; or
- two tablets three times a week taken on alternate days; or
- two tablets twice daily three times a week taken on alternate days.
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Children 6 to 12 years:

- one tablet twice daily on each day of the week; or
- one tablet twice daily three times a week on alternate days; or
- one tablet twice daily three times a week on consecutive days; or

- two tablets once a day three times a week on consecutive days.

Use in children

The recommended dose for children is according to the child's age and body weight provided in the table below:

Age and weight:	Daily dose:
Children aged 6 to 12 years (OR body weight >27 kg)	One tablet every 12 hours
Children > 12 years (OR body weight > 53 kg)	Two tablets every 12 hours

Patients with kidney problems

If your kidneys are not working very well, your doctor may change the dose and test your blood to see if the medicine is working properly.

Elderly

Care should be taken as the elderly may get more side effects, which could be serious if they have existing conditions or are taking other medicines.

Taking Co-Trimoxazole Tablets long term

If you are taking Co-Trimoxazole Tablets for long periods, blood tests may be carried out. The doctor may also prescribe an additional drug, folic acid, for you to take.

If you take more Co-Trimoxazole Tablets than you should

If you take more tablets than you should you may feel nauseous (sick) and confused.

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the container and any remaining tablets with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Co-Trimoxazole Tablets

If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Co-Trimoxazole Tablets

Do not stop just because you feel better. If you stop too soon, the infection may come back. Keep taking the tablets until the prescribed course is finished.

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.

STOP taking the tablets and **seek medical help immediately** if you have any of the following **allergic reactions**:

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis and widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organ involvement (Drug Reaction with

Eosinophilia and Systemic Symptoms which is also known as 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 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)
- a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).
- 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.
- Call the emergency department immediately if you experience multiple symptoms such as fever, very low blood pressure or increased heart rate after taking this drug as it may be a sign of shock

Seek immediate medical attention if you have any of the following symptoms:

- sudden headache, stiff neck, fever, sensitivity to bright light, drowsiness and muscle pain, with or without a rash
- pinpoint red spots on the skin, unusual purple bruise-like rash on the skin or in the mouth, unusual or heavy bleeding
- fever, sore throat, mouth ulcers, repeated infections or infections that will not go away
- cough, feeling breathless, chest pain
- swollen legs or joints, feeling tired
- pain behind the ribs radiating towards the back, often worse when lying down, nausea, vomiting, fever
- severe stomach cramps, watery and severe diarrhoea which may be bloody
- yellowing of the skin or eyes, pale faeces and dark urine, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness
- seizures (fits).

Tell your doctor if you get any of the following side effects:

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

- increased amount of potassium in the blood. You cannot feel or see this but your doctor may test your blood for this.

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

- headache
- nausea
- diarrhoea
- skin rashes
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore, itchy vagina with vaginal discharge)
- thrush affecting the penis.

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

- vomiting.

Very rare side effects (may affect up to 1 in 10,000 people):

- reactions to the sun. Skin may become red, painful and swollen – do not sunbathe, use a sunbed or expose your skin to UV light
- allergic-like reaction (skin rash, hives, fever and joint pain) which may happen after you stop taking co-trimoxazole
- fever
- depression or hallucinations
- tingling or numbness in the hands and feet

- feeling unsteady or dizzy, head-spins, lack of co-ordination
- ringing in the ears
- inflamed and sore tongue, sore mouth, difficulty chewing and eating
- butterfly-shaped rash over the nose and cheeks, made worse by exposure to the sun. Tiredness and joint pains
- low sugar level (feeling hungry, nervous, sweating, trembling)
- low sodium level (headache, nausea, vomiting, lethargy, muscle cramps). Blood may be tested for this
- lack of appetite, weight loss
- muscle weakness or pain
- joint pain
- kidney changes. Blood and urine may be tested for this.

Not known (frequency cannot be estimated from the available data):

- drug reaction with eosinophilia and systemic symptoms (DRESS).
- plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweets syndrome).

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-Trimoxazole Tablets

Keep this medicine out of the sight and reach of children.

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Co-Trimoxazole Tablets contain

- The active substances are sulfamethoxazole (400 mg) and trimethoprim (80 mg).
- The other ingredients are starch, magnesium stearate, colloidal silica and sodium starch glycollate. See end of section 2 for further information on sodium.

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

Co-Trimoxazole Tablets are white bi-convex tablets with a break line on one side. They are available in packs of 28, 100, 500 or 1,000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chemidex Pharma Ltd., trading as Essential Generics, 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB, United Kingdom.

Manufacturer

Dales Pharmaceuticals Ltd., Snaygill Industrial Estate, Keighley Road, Skipton, Yorkshire, BD23 2RW, United Kingdom.

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