

- Pains in your stomach, which may occur with blood in your faeces (poo)
- Problems with your urine. Difficulty passing urine. Passing more or less urine than usual. Blood or cloudiness in your urine
- Kidney problems
- Fits (convulsions or seizures)
- Seeing strange or unusual sights (hallucinations).

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

- Plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweets syndrome)
- Psychotic disorder (a mental state in which you may lose touch with reality).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Very Common (may affect 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 (may affect up to 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 (may affect up to 1 in 100 people):

- Being sick (vomiting).

Very Rare (may affect up to 1 in 10,000 people):

- Fever (high temperature) or frequent infections
- 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
- Pains in your chest, muscles or joints and muscle weakness
- Arthritis
- Sudden headache or stiffness of your neck, accompanied by fever (high temperature)
- Problems controlling your movements
- Feeling unsteady or giddy
- Ringing or other unusual sounds in your ears

- Tingling or numbness in your hands and feet
- Depression
- Muscle pain and/or muscle weakness in HIV patients
- Loss of appetite
- Cough
- Abnormal chemical levels in the blood (e.g. of potassium, sodium, calcium, urea).

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 Website: 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. Store below 25°C in a dry place and protect from light.

Do not take this medicine after the expiry date which is stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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 (the ingredients that make the tablets work) are 80mg of trimethoprim and 400mg of sulfamethoxazole.
- The other ingredients are docusate sodium, magnesium stearate, maize starch, silica, sodium lauryl sulfate and stearic acid.

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

Co-trimoxazole Tablets 80/400mg are white, circular, biconvex uncoated tablets, impressed "C" on one face and the identifying letters "CF" on either side of a central division line on the reverse. Pack sizes are 28 tablets.

Marketing Authorisation Holder and Manufacturer

Accord, Barnstaple, EX32 8NS, UK

This leaflet was last revised in March 2021.

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Package leaflet: Information for the patient

Co-trimoxazole tablets 80/400mg

(Trimethoprim and Sulfamethoxazole)

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
- 3 How to take Co-trimoxazole tablets
- 4 Possible side effects
- 5 How to store Co-trimoxazole tablets
- 6 Contents of the pack and other information

1 What Co-trimoxazole tablets are and what they are used for

Co-trimoxazole 80mg/400mg 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 if:

- you are **allergic** to sulfamethoxazole, trimethoprim or Co-trimoxazole or any of the other ingredients of this medicine (listed in 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-trimoxazole if you:

- have severe allergies or asthma
- have been told that you have a rare blood problem called porphyria, which can affect your skin or nervous system
- 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

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- have ever had jaundice which can cause yellowing of your skin or the whites of your eyes
- have a problem with your metabolism called phenylketonuria and are not on a special diet to help your condition
- are elderly
- have a kidney disease
- are underweight or malnourished
- have been told by your doctor that you have a lot of potassium in your blood. 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.

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 and 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. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis 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
- at the start of treatment, the occurrence of a generalised skin redness with pustules, accompanied by fever, should raise the suspicion of a serious reaction called acute generalised exanthematous pustulosis (AGEP) (see section 4).

Other medicines and Co-trimoxazole tablets

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) such as spironolactone, 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 (sulfonylureas) 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.

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 or pharmacist for advice before taking this medicine.

Driving and using machines

Effects on the ability to drive and operate machinery in patients taking this medicine have not been studied.

Information on sodium content

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

3 How to take Co-trimoxazole tablets

Always take this medicine exactly 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
>18 years old	2 Tablets every 12 hours

Children over 12 years

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

>12 years and over OR >Weighing 53kg or above	Two tablets in a morning and two tablets in an evening
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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.

Co-trimoxazole 80mg/400mg tablets are not usually given to children under 12 years old. If they have been given to your child under 12 years please speak to your doctor or pharmacist for more information.

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.

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 Co-trimoxazole tablets and tell your doctor immediately if you have an allergic reaction. Signs of an allergic reaction include:

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

- Sudden wheeziness or difficulty 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.

Stop taking Co-trimoxazole tablets and tell your doctor immediately if you develop the following symptoms:

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

- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) or on much of the body surface (toxic epidermal necrolysis) (see Warnings and precautions)
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis (AGEP)) (see section 2)
- Mouth ulcers, cold sores and ulcers or soreness of your tongue
- Skin lumps or hives (raised, red or white, itchy patches of skin)
- Jaundice (the skin and the whites of your eyes turn yellow). This can occur at the same time as unexpected bleeding or bruising