Package leaflet: Information for the patient

Co-Trimoxazole 80 mg/400 mg per 5 ml Adult Suspension
Co-trimoxazole

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

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

Co-Trimoxazole 80 mg/400 mg per 5 ml Adult Suspension (called 'Co-Trimoxazole' in this leaflet) is a combination of two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by certain 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 PJP) caused by *Pneumocystis jirovecii*.
- Infections caused by Toxoplasma (toxoplasmosis).

Co-Trimoxazole can be used to treat:
- Urinary bladder or urinary tract infections (water infections).
- Respiratory tract infections such as bronchitis.
- Ear infections such as otitis media.
- An infection called nocardiosis which can affect the lungs, skin and brain.

Consideration should be given of official guidance on the appropriate use of antibacterial agents.

Co-Trimoxazole Adult Suspension is indicated in children (>12 to <18 years old) and adults (>18 years old).

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

Do not take Co-Trimoxazole
- If you are allergic to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to sulphonamide medicines. Examples include sulphonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – a water tablet).
- If you have severe liver or severe kidney problems.
- If you have ever had a problem with your blood causing bruises or bleeding (thrombocytopenia).
- If 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 pregnant (first 3 months) or might be pregnant.

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Co-Trimoxazole:
- If you have severe allergies or asthma.
- Potentially life-threatening skin rashes (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 appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Co-Trimoxazole.
- 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 generalised acute exanthematous pustulosis (AGEP) (see section 4).
- 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.
- If you have developed Stevens-Johnson syndrome, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms 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 (see section 4).
- 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.
- If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately.
- If you have been told that you are at risk for a rare blood disorder called porphyria.
- If 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.
- If you have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- If you have a problem with your metabolism called phenylketonuria and are not on a special diet to help your condition.
- If you are an older person.
- If you are underweight or malnourished.
- If you have been told by your doctor that you have a lot of potassium in your blood.
- If you have a kidney disease.
- If you have severe allergy or bronchial asthma.
- If you have a severe blood disorder, such as a low number of red blood cells (anaemia), a low number of white blood cells (leucopenia) or a low number of platelets, which may cause bleeding and bruising (thrombocytopenia).Concomitant administration of Co-Trimoxazole 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.

Other medicines and Co-Trimoxazole
Tell your doctor or pharmacist if you are taking, have recently taken or may take any other medicines This is because Co-Trimoxazole can affect the way some medicines work. Also some other medicines can affect the way Co-Trimoxazole works.
In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- 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.
- 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, such as spironolactone), steroids (like prednisolone) and digoxin or ACE inhibitors (may be used to treat high blood pressure or some heart problems).
- Azathioprine, may be used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease.
- Methotrexate, a medicine used to treat certain cancers or certain diseases affecting your immune system.
- Rifampicin, an antibiotic.
- Folinic acid.
- Contraceptive medicines.

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 or pharmacist for advice before taking this medicine.

This medicine should not be taken during first three months of pregnancy. Treatment with trimethoprim in the first three months of pregnancy may increase the risk of miscarriage. Children born to mothers treated with trimethoprim during the first trimester of pregnancy may have an increased risk of birth defects, in particular neural tube defects (where the spine and spinal cord do not form properly), oral clefts (where the lip and palate do not form properly) and defects affecting the heart.

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

Co-Trimoxazole contains

- 2.5 g sucrose in every 5 ml spoonful. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), contact your doctor before taking this medicinal product.
- A small amount of ethanol (alcohol), less than 100 mg per ml spoonful.
- Methyl hydroxybenzoate, which may cause allergic reactions (possibly delayed).
- Less than 1 mmol sodium (23 mg) per 5 ml, i.e. essentially 'sodium free'.

3. How to take Co-Trimoxazole

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

Standard dose

Standard dosage recommendations for acute infections

Adults (>18 years old)

Standard Dosage	
Age	**Adult Suspension**
>18 years old	10 ml every 12 hours

Children over 12 years old (>12 to <18 years old)

The standard dosage for children is equivalent to approximately 6 mg trimethoprim and 30 mg sulfamethoxazole per kg body weight per day, given in two equally divided doses. The schedules for children are according to the child's age and body weight provided in the table below:

Paediatric Dosage	
Age	**Adult Suspension**
>12 to <18 years old	10 ml every 12 hours
Weight	**Adult Suspension**
>53 kg	Two 5 ml spoonfuls in the morning and two 5 ml spoonfuls in the evening
>40 kg	One 5 ml + one 2.5ml spoonful in the morning and one 5 ml + one 2.5 ml spoonful in the evening
>27 kg	One 5 ml spoonful in the morning and one 5 ml spoonful in the evening
>13 kg	One 2.5 ml spoonful in the morning and one 2.5 ml spoonful in the evening

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 80 mg/400 mg per 5 ml Adult Suspension is not usually given to children under 12 years old. If this has 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 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 jirovecii
- 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.
- Take blood to test whether the medicine is working properly.

If you take Co-Trimoxazole 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.

If you take more Co-Trimoxazole than you should

If you take more Co-Trimoxazole 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 much Co-Trimoxazole you may

- Feel or be sick.
- Feel dizzy or confused.

If you forget to take Co-Trimoxazole

- 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, Co-Trimoxazole can cause side effects, although not everybody gets them.
You may experience the following side effects with this medicine.

Stop taking Co-Trimoxazole and tell your doctor immediately if you notice any of the following symptoms:

- 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.
- reddish patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu like symptoms (Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN)).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Very Common (more than 1 in 10 people)

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

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.

Common (less than 1 in 10 people)

- A fungal infection called thrush or candidiasis which can affect your mouth or vagina.
- Headache.
- Feeling sick (nausea).
- Diarrhoea.
- Skin rashes.

Uncommon (less than 1 in 100)

- Being sick (vomiting).

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

- Fever (high temperature) or frequent infections.
- Sudden wheeziness or difficulty breathing.
- Very rare cases of redness generalising to the whole body (generalised acute 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).
- 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.
- Muscle pain and/or muscle weakness in HIV patients.
- Loss of appetite.

Not known (frequency cannot be estimated from the available data)
- Psychotic disorder (a mental state in which you may lose touch with reality)
- Plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweet's syndrome).

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.

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

Keep this medicine out of the sight and reach of children.
Keep away from direct heat or sunlight.
Do not store above 25°C.
Do not take the suspension after the expiry date shown on the bottle label and carton.
Store in the original package with this leaflet.
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 protect the environment.

6. Contents of the pack and other information

What Co-Trimoxazole contains

- Co-Trimoxazole is made up of two different medicines called sulfamethoxazole and trimethoprim. These medicines are sometimes given the combined name co-trimoxazole.
- The other ingredients Co-Trimoxazole 80 mg/400 mg per 5 ml Adult Suspension are: sucrose, glycerol (E422), cellulose (E460), sodium carmellose, methyl hydroxybenzoate (E218), saccharin sodium (E954), ammonium glycyrrhizinate, star anise oil, ethanol (alcohol), vanilla flavour, polysorbate 80 (E433) and purified water.

What Co-Trimoxazole looks like and contents of the pack

Co-Trimoxazole 80 mg/400 mg per 5 ml Adult Suspension is supplied to you in an amber-coloured glass bottle, containing 100 ml of an off-white liquid. The medicine comes with a double-ended measuring spoon. One end of the spoon will give you 5 ml of the suspension and the other will give you 2.5 ml.
Each 5 ml of Co-Trimoxazole 80 mg/400 mg per 5ml Adult Suspension contains 400mg sulfamethoxazole and 80 mg trimethoprim.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder:
Aspen Pharma Trading Limited
3016 Lake Drive
Citywest Business Campus
Dublin 24, Ireland

Manufacturer:
Aspen Bad Oldesloe GmbH
Industriestrasse 32-36,
D-23843 Bad Oldesloe,
Germany

Medical information enquiries

For any Medical Information enquires about this product, please contact:
24 Hour Helpline +441748 828 391 (free phone UK only 0800 0087 392)

This leaflet was last revised in January 2026.

Other source of information:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
Braille RNIB Helpline **0800 198 5000 (UK only).**
Please be ready to give the following information:
Product name Co-Trimoxazole 80 mg/400 mg per 5 ml Adult Suspension
Reference number PL 39699/0038
This is a service provided by the Royal National Institute of Blind People.