

Package leaflet: Information for the patient
Co-Trimoxazole 40 mg/200 mg per 5ml Paediatric Suspension
Co-trimoxazole

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for them.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child.
- If your child gets any side effects, talk to your child's 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 your child takes Co-Trimoxazole
3. How to give 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 40 mg/200 mg per 5 ml Paediatric 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 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 a bacteria called *Pneumocystis jirovecii*.
- Infections caused by a bacteria called 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 Paediatric Suspension is indicated in children aged 12 years and under (infants (>6 weeks to <2 years old) and children (>2 to <12 years old).

2. What you need to know before your child takes Co-Trimoxazole

Your child should not take Co-Trimoxazole:

- If they are allergic to sulfamethoxazole, trimethoprim or co-trimoxazole or any of the other ingredients of this medicine (listed in section 6).
- If they are allergic to sulphonamide medicines. Examples include sulphonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – a water tablet).
- If they have severe liver or severe kidney problems.
- If they have ever had a problem with their blood causing bruises or bleeding (thrombocytopenia).
- If you have been told that your child has a rare blood problem called porphyria, which can affect their 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 your child, talk to their doctor or pharmacist before they take Co-Trimoxazole.

Warnings and precautions

Talk to your child's doctor or pharmacist before taking Co-Trimoxazole:

- If they have severe allergies or asthma.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms) 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.
- 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 your child has developed Stevens-Johnson syndrome, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms with the use of Co-Trimoxazole your child must not be re-started on Co-Trimoxazole at any time.
- If your child develops a rash or these skin symptoms, stop giving Co-Trimoxazole, seek urgent advice from a doctor and tell him that your child is taking this medicine.
- **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 your child is at risk for a rare blood disorder called porphyria.
- If they don't have enough folic acid (a vitamin) in their body - which can make their skin pale and make them feel tired, weak and breathless. This is known as anaemia.
- If they have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- If they have a problem with their metabolism called phenylketonuria and are not on a special diet to help their condition.
- If they are underweight or malnourished.
- If you have been told by your child's doctor that your child has a lot of potassium in their blood. 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.
- If they have a kidney disease.
- If they have severe allergy or bronchial asthma.
- If your child has 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).

Other medicines and Co-Trimoxazole

Tell your child's doctor or pharmacist if your child is taking, has recently taken or might 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 child's doctor or pharmacist if your child is taking any of the following medicines:

- Diuretics (water tablets), which help increase the amount of urine produced.
- 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 the 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 the blood, such as diuretics (water tablets, which help increase the amount of urine produced, 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 the immune system.
- Folinic acid.
- Rifampicin, an antibiotic.
- Contraceptive medicines.

Co-Trimoxazole with food and drink

Your child should take Co-Trimoxazole with some food or drink. This will stop them feeling sick (nausea) or having diarrhoea. Although it is better to take it with food, they can still take it on an empty stomach. Make sure your child drinks plenty of fluid such as water while they are taking Co-Trimoxazole.

Co-Trimoxazole contains

3.25 g sorbitol in every 5 ml spoonful. If you have been told by your child's doctor that they cannot tolerate or digest some sugars (has an intolerance to some sugars), contact your child's doctor before giving this medicinal product to your child.

- A small amount of ethanol (alcohol), less than 100 mg per 5 ml spoonful.
- Methyl hydroxybenzoate, which may cause allergic reactions (possibly delayed).
- Benzoate, which may increase the risk of jaundice in newborn babies.
- Less than 1 mmol sodium (23 mg) per 5 ml, i.e. essentially 'sodium free'.

3. How to give Co-Trimoxazole

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

Standard Dose

Standard dosage recommendations for acute infections

Children aged 12 years and under (infants (>6 weeks to <2 years old) and children (>2 to <12 years old):

The dosage for children is equivalent to approximately 6 mg trimethoprim and 30 mg sulfamethoxazole per kg body weight per day.

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

Standard Dosage	
Age	Paediatric Suspension
6 to 12 years	two 5 ml spoonfuls in a morning and two 5 ml spoonfuls in an evening
6 months to 5 years	one 5 ml spoonful in a morning and one 5 ml spoonful in an evening
6 weeks to 5 months	one 2.5 ml spoonful in a morning and one 2.5 ml spoonful in an evening
Weight	Paediatric Suspension
>27 kg	Two 5 ml spoonfuls in the morning and two 5 ml spoonfuls in the evening
>20 kg	One 5 ml + one 2.5ml spoonful in the morning and one 5 ml + one 2.5 ml spoonful in the evening
>13 kg	One 5 ml spoonful in the morning and one 5 ml spoonful in the evening
>7 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 your child finishes the course of Co-Trimoxazole which their doctor has prescribed.

Special dose

The dose of Co-Trimoxazole and how long your child needs to take it depends on the infection they have and how bad it is. Your child's 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 your child takes Co-Trimoxazole for a long time their doctor may

- Take blood to test whether the medicine is working properly.
- Prescribe folic acid (a vitamin) for your child to take at the same time as Co-Trimoxazole.

If your child takes more Co-Trimoxazole than they should

If your child takes more Co-Trimoxazole than they should, talk to their doctor or go to a hospital straight away. Take the medicine pack with you.

If your child has taken too much Co-Trimoxazole they may

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

If you forget to give your child Co-Trimoxazole

If a dose is forgotten, your child should take it as soon as possible.

Do not give your child a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Co-Trimoxazole can cause side effects, although not everybody gets them.

Your child may experience the following side effects with this medicine.

Stop giving your child Co-Trimoxazole and tell your child's doctor immediately if your child has 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

Allergic reactions

- 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)

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

Common (less than 1 in 10 people)

- A fungal infection called thrush or candidiasis which can affect your child's 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.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see Warnings and precautions).
- 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 the tongue.
- Skin lumps or hives (raised, red or white, itchy patches of skin).
- Blisters on the skin or inside the mouth, nose, vagina or bottom.
- Inflammation of the eye which causes pain and redness.
- The appearance of a rash or sunburn when your child has been outside (even on a cloudy day).
- Low levels of sodium in the blood.
- Changes in blood tests.
- Feeling weak, tired or listless, pale skin (anaemia).
- Heart problems.
- Jaundice (the skin and the whites of the eyes turn yellow). This can occur at the same time as unexpected bleeding or bruising.
- Pains in the stomach, which can occur with blood in the faeces (poo).
- Pains in the chest, muscles or joints and muscle weakness.
- Arthritis.
- Problems with the urine. Difficulty passing urine. Passing more or less urine than usual. Blood or cloudiness in the urine.
- Kidney problems.
- Sudden headache or stiffness of the neck, accompanied by fever (high temperature).
- Problems controlling movements.
- Fits (convulsions or seizures).
- Feeling unsteady or giddy.
- Ringing or other unusual sounds in the ears.
- Tingling or numbness in the hands and feet.
- Seeing strange or unusual sights (hallucinations).
- Depression.
- Muscle pain and/or muscle weakness in HIV patients.
- Loss of appetite.

Unknown frequency (cannot be estimated from the available data)

- Psychotic disorder (a mental state in which you may lose touch with reality)(changes in behaviour)

- Plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweets syndrome).
- Drug reaction with eosinophilia and systemic symptoms (an allergic type reaction in which you may develop fever, skin rash, and abnormalities in blood and liver function tests (these may be signs of a multi-organ sensitivity disorder)).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's 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 use 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 of Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension are: sorbitol solution (E420 ii), glycerol (E422), dispersible cellulose (E460), sodium carmellose, methyl hydroxybenzoate (E218), sodium benzoate (E211), saccharin sodium (E954), ethanol (alcohol), vanilla flavour, banana flavour, polysorbate 80 (E433) and purified water.

What Co-Trimoxazole looks like and contents of the pack

Co-Trimoxazole 40 mg/200 mg per 5 ml Paediatric Suspension is supplied to you in an amber-coloured glass bottle, containing 100 ml or 30 ml of an off-white liquid, which smells of banana and vanilla. 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 40 mg/200 mg per 5 ml Paediatric Suspension contains 200 mg sulfamethoxazole and 40 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 July 2021.

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 40 mg/200 mg per 5 ml Paediatric Suspension

Reference number: **PL 39699/0037**

This is a service provided by the Royal National Institute of Blind People.