

Package leaflet: Information for the patient

Co-Trimoxazole 16 mg/80 mg per ml for Infusion

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 are given Co-Trimoxazole
3. How Co-Trimoxazole is given
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 16 mg/80 mg per ml for Infusion (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 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).
- an infection called nocardiosis which can affect the lungs, skin and brain.

Co-Trimoxazole 16 mg/80 mg per ml for infusion will usually only be given to you if you are unable to take medicines by mouth.

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

Co-Trimoxazole for Infusion is indicated in children (≥ 6 weeks) and adults.

2. What you need to know before you are given Co-Trimoxazole

Co-Trimoxazole is contraindicated in the following situations:

- 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 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 being given Co-Trimoxazole:

- If you 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 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, seek immediate advice from a doctor and tell him that you are 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 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 elderly.
- If you are underweight or malnourished.
- If you have been told by your doctor that you have a lot of potassium in your 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 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).

Other medicines and Co-Trimoxazole

Tell your doctor or pharmacist if you are taking, have 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 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.
- Folic acid.
- Contraceptive medicines.

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.

See following section for more information about ethanol content in the formulation.

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

- Sodium metabisulphite. This can cause allergic type reactions including skin rash; swelling of eyelids, face or lips or difficulty in breathing. This is rare, but you may be more at risk if you suffer from allergies or asthma.
- 13.2 vol% ethanol (alcohol). There can be up to 521 mg per dose. This is equivalent to 13.22 ml of beer, or 5.5 ml of wine. It may be harmful if you are alcoholic. The ethanol content should also be taken in to account if you are pregnant or breast-feeding, a child or if you have liver problems or epilepsy.
- 1.7 mmoles (or 38.87 mg) of sodium. To be taken into consideration by patients on a sodium controlled diet.

3. How Co-Trimoxazole is given

You will never be expected to give yourself this medicine. It will always be given to you by a person who is trained to do so.

Co-Trimoxazole 16 mg/80 mg per ml for Infusion will be given to you as a continuous infusion into your vein. This is where the drug is slowly given to you over a period of time.

Before the medicine is given to you it will be diluted.

The dose you will be given, and the frequency of the dose will depend on:

- the type of infection you have.
- your weight.
- your age.

Posology

Standard dosage recommendations for acute infections

Treatment should be continued until you have been free from symptoms for 2 days. It is likely you will require treatment for at least 5 days. In case of severe infections, dosage may be increased by 50%.

Adults and children over 12 years :

STANDARD DOSAGE: 2 ampoules (10 ml) every 12 hours

Children aged 12 years and under:

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.

Age	Dosage
6 weeks to 5 months	1.25 mL every 12 hours.
6 months to 5 years	2.5 mL every 12 hours
6 to 12 years	5.0 mL every 12 hours.

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 are given more Co-Trimoxazole than you should

If you think you have been given more Co-Trimoxazole, talk to your doctor or nurse straight away.

If you have been given too much Co-Trimoxazole you may:

- feel or be sick.
- feel dizzy or confused.

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 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:

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

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.

Very Common (more than 1 in 10 people)

- High levels of potassium in your 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 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 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 (stools)
- 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

Unknown 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 (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 doctor or nurse.

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 30°C.
- Do not have this medicine after the expiry date shown on the carton and label.
- Store in the original package with this leaflet.

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.
- The other ingredients of Co-Trimoxazole 16 mg/80 mg per mL for Infusion are: propylene glycol (E1520), tromethamine, sodium hydroxide (E524), sodium metabisulphite (E223), ethanol, Water for Injections.

What Co-Trimoxazole looks like and contents of the pack

Co-Trimoxazole is available in 5 ml glass ampoules.
Each 5 ml ampoule contains 400 mg sulfamethoxazole and 80 mg trimethoprim.
The ampoules are supplied in packs of 10.

Marketing Authorisation Holder And Manufacturer

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

Manufacturer:
Biologici Italia Laboratories S.r.l
Via Filippo Serpero
2-20060 Masate (Mi), Italy

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 2025.

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 16 mg/80 mg per ml for Infusion

Reference number: PL 39699/0044

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

The following information is intended for healthcare professionals only
Co-Trimoxazole 16 mg/80 mg per mL for Infusion

Trimethoprim-sulfamethoxazole

DOSAGE AND ADMINISTRATION INFORMATION ONLY

Please refer to the Summary of Product Characteristics for complete prescribing information.
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QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL of Co-Trimoxazole 16 mg/80 mg per mL for Infusion contains 80 mg Trimethoprim and 400 mg Sulfamethoxazole.

Excipients:

This product contains 1.7 mmols of sodium, 13.2 vol % ethanol (alcohol) per 5 mL and sodium metabisulphite.

For the full list of excipients, see section Pharmaceutical Particulars.

PHARMACEUTICAL FORM

Solution for Infusion

A clear liquid.

POSOLOGY AND METHOD OF ADMINISTRATION

Posology

Standard dosage recommendations for acute infections

Treatment should be continued until the patient has been symptom free for two days; the majority will require treatment for at least 5 days.

For severe infections in all age groups, dosage may be increased by 50%.

Adults and children over 12 years:

STANDARD DOSAGE: 2 ampoules (10 ml) every 12 hours

Children aged 12 years and under:

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.

Age	Dosage
6 weeks to 5 months	1.25 mL every 12 hours.
6 months to 5 years	2.5 mL every 12 hours
6 to 12 years	5.0 mL every 12 hours.

Elderly:

See SPC section 4.4 Special warnings and precautions for use.

Impaired hepatic function:

No data are available relating to dosage in patients with impaired hepatic function. Caution should be exercised when treating patients with severe hepatic impairment as there may be changes in the absorption and biotransformation of trimethoprim and sulfamethoxazole.

Impaired renal function:

Dosage recommendation:

Adults and children over 12 years:

Creatinine Clearance (ml/min)	Recommended Dosage
> than 30	2 ampoules (10 mL) every 12 hours
15-30	1 ampoule (5 mL) every 12 hours
< 15	Not recommended.

No information available for children aged 12 years and under with renal failure. See section 5.2 (SmPC) for the pharmacokinetics in the paediatric population with normal renal function of both components of Co-Trimoxazole, TMP and SMZ.

Measurements of plasma concentrations of sulfamethoxazole at intervals of 2 to 3 days are recommended in samples obtained 12 hours after administration of Co-Trimoxazole 16 mg/80 mg per

ml for Infusion. If the concentration of total sulfamethoxazole exceeds 150 micrograms/mL then treatment should be interrupted until the value falls below 120 micrograms/mL.

Pneumocystis jirovecii (*P. jirovecii*) *pneumonitis*:

Treatment :

15-20 mg trimethoprim and 75-100 mg sulfamethoxazole per kg of bodyweight per day in two or more divided doses. Therapy should be changed to the oral route as soon as possible and continued for a total treatment period of two weeks. The aim is to obtain peak plasma or serum levels of trimethoprim of greater than or equal to 5 microgram/ml (verified in patients receiving 1-hour infusions of intravenous Co-Trimoxazole). (see SPC section 4.8 Undesirable effects)

Prevention: Standard dosage as described under acute infections for the duration of the period at risk.

Nocardiosis:

There is no consensus on the most appropriate dosage. Adult doses of 6 to 8 tablets daily for up to 3 months have been used (one tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim).

Toxoplasmosis:

There is no consensus on the most appropriate dosage for the treatment or prophylaxis of this condition. The decision should be based on clinical experience. For prophylaxis, however, the dosages suggested for prevention of *Pneumocystis jirovecii* pneumonitis may be appropriate.

Method of Administration:

Co-Trimoxazole is for administration only by the intravenous route and must be diluted before administration.

It is intended that Co-Trimoxazole for Infusion should be used only during such a period as the patient is unable to accept oral therapy, where initiation of treatment is particularly urgent or for convenience if the patient is already receiving intravenous fluids. Although Co-Trimoxazole for Infusion is useful in critically ill patients, there may be no therapeutic advantage over the oral preparation.

For instructions on dilution of the product before administration, see special precautions for disposal and other handling.

OVERDOSE

Symptoms and signs

The maximum tolerated dose in humans is unknown.

Nausea, vomiting, dizziness and confusion are likely symptoms of overdosage. Bone marrow depression has been reported in acute trimethoprim overdosage.

Treatment

In cases of known, suspected or accidental overdosage, stop therapy.

Dependent on the status of renal function, administration of fluids is recommended if urine output is low.

Both trimethoprim and active sulfamethoxazole are dialysable by renal dialysis. Peritoneal dialysis is not effective.

Acidification of the urine will increase the elimination of trimethoprim. Inducing diuresis plus alkalinisation of urine will enhance the elimination of sulfamethoxazole. Alkalinisation will reduce the rate of elimination of trimethoprim. Calcium folinate (5 to 10 mg/day) will reverse any folate deficiency effect of trimethoprim on the bone marrow should this occur. General supportive measures are recommended.

PHARMACEUTICAL PARTICULARS

List of excipients

Propylene Glycol (E1520) Ph Eur
Tromethamine USP
Sodium Hydroxide (E524) BP
Sodium Metabisulphite (E223) BP
Ethanol BP
Water for Injections Ph Eur

Incompatibilities

None known.

Shelf life

36 months

Special precautions for storage

Store below 30°C.
Protect from light.

Nature and contents of container

Neutral glass ampoules (5 mL nominal fill volume)
Pack size: 10 x 5 mL ampoules

Special precautions for disposal and other handling

Co-Trimoxazole for infusion must be diluted before administration.

DILUTION SHOULD BE CARRIED OUT IMMEDIATELY BEFORE USE. After adding Co-Trimoxazole 16 mg/80 mg per mL for Infusion to the infusion solution, shake thoroughly to ensure complete mixing. If visible turbidity or crystallisation appears at any time before or during an infusion, the mixture should be discarded.

It is recommended that Co-Trimoxazole 16 mg/80 mg per ml for Infusion is diluted according to the following schedules:

One ampoule (5 ml) added to 125 ml infusion solution.
Two ampoules (10 ml) added to 250 ml infusion solution.
Three ampoules (15 ml) added to 500 ml infusion solution.

Co-Trimoxazole 16 mg/80 mg per ml for Infusion is known to be compatible, when diluted as recommended above, with the following fluids:

Glucose Intravenous Infusion BP (5% w/v and 10% w/v);
Sodium Chloride Intravenous Infusion BP (0.9% w/v);
Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion BP;
Dextran 70 Intravenous Infusion BP (6% w/v) in glucose (5% w/v) or normal saline;
Dextran 40 Intravenous Infusion BP (10% w/v) in glucose (5% w/v) or normal saline;

Ringer's Solution for Injection BPC 1959.

The pH of the solution is in the range 9.5 to 11.0.

No other substance should be mixed with the infusion.

The duration of the infusion should be approximately one to one and a half hours, but this should be balanced against the fluid requirements of the patient.

When fluid restriction is necessary, Co-Trimoxazole 16 mg/80 mg per ml for Infusion may be administered at a higher concentration, 5 ml diluted with 75 ml of glucose 5% w/v in water. The resultant solution, whilst being clear to the naked eye, may on occasion exceed the BP limits set for particulate matter in large volume parenterals. The solution should be infused over a period not exceeding one hour. Discard any unused solution.

Co-Trimoxazole 16 mg/80 mg per ml for Infusion is licenced for sale in the UK.

MARKETING AUTHORISATION HOLDER

Aspen Pharma Trading Limited
3016 Lake Drive,
Citywest Business Campus,
Dublin 24,
Ireland

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