

The standard dosage for children is equivalent to approximately 6mg trimethoprim and 30mg 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 weight and provided in the tables below:

STANDARD DOSAGE	
Age	Solution for Infusion
>12 to <18 years old	2 ampoules (10ml) every 12 hours
Weight	Solution for Infusion
>53kg	2 ampoules (10ml) every 12 hours

Age	Dosage
6 weeks to 5 months	1.25ml every 12 hours
6 months to 5 years	2.5ml every 12 hours
6 to 12 years	5.0ml every 12 hours
Weight	Dosage
>7kg	1.25ml every 12 hours
>13kg	2.5ml every 12 hours
>27kg	5.0ml every 12 hours

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

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

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. The chance 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 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 of 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 |
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| <ul style="list-style-type: none">Keep this medicine out of the sight and reach of children. This medicinal product does not require any special temperature storage conditions. Do not refrigerate or freeze. Store the ampoules in the outer carton in order to protect from light. Do not use this medicine after the expiry date shown on the carton and label. | |

- | 6 | Contents of the pack and other information |
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What Co-trimoxazole contains

- Co-trimoxazole is made up of two different medicines called sulfamethoxazole and trimethoprim.

- The other ingredients of Co-trimoxazole 16mg/80mg per ml solution for infusion are: propylene glycol (E1520), tromethamine, sodium hydroxide (E524), ethanol, water for injections.

What Co-trimoxazole looks like and contents of the pack

Co-trimoxazole is available in 5ml type I colourless glass ampoules.

Each 5ml ampoule contains 400mg sulfamethoxazole and 80mg trimethoprim. The ampoules are supplied in packs of 10.

Marketing Authorisation Holder and Manufacturer

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Other sources of information

This leaflet is available in alternative formats such as audio, CD-ROM or large print. Please contact Aspire Pharma Ltd via telephone: (+44) 01730 231148 or email: medinfo@aspirepharma.co.uk for more information.

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

Glucose Intravenous Infusion (5% w/v and 10% w/v);
Sodium Chloride Intravenous Infusion (0.9% w/v);
Dextran 40 Intravenous Infusion (10% w/v) in glucose (5% w/v).
Ringers Solutions for Injection.

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 16mg/80mg per ml solution for infusion may be administered at a higher concentration, 5ml diluted with 75ml 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.

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