The information contained in this leaflet is intended for health professionals.

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

**Indications**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Prevention of Pneumocystis jiroveci pneumonitis may be appropriate.
- Treatment and prophylaxis of Toxoplasmosis:
  - Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- 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 caused by certain antibiotics.

**Dosage and administration**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- For intravenous use only. Do not give by intramuscular injection.
- Initial dosage: 30 mg sulfamethoxazole per kg bodyweight per 24 hours, given in two divided doses.
- Children aged 12 years and under:
  - 2 ampoules (10 ml) every 12 hours.

**Contra-indications**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Hypersensitivity to trimethoprim, sulfamethoxazole or any of the other ingredients of the preparation.
- Hyperbilirubinaemia or bilirubinuria in neonates.
- Pregnancy and lactation:
  - Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Children:
  - Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.

**Side effects**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Possible side effects:
  - Allergic reactions: skin rashes, urticaria, angioedema.
  - Gastrointestinal disturbances: nausea, vomiting, diarrhea.
  - Nephrotoxicity: acute renal failure, interstitial nephritis.
  - Hematological: agranulocytosis, neutropenia, thrombocytopenia.
  - Hepatic: hepatitis, jaundice.
  - Central nervous system: headache, dizziness, peripheral neuropathy.
  - Ocular: reversible hyperplasia.

**Warnings and precautions**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- If you have been given too much Co-trimoxazole 16 mg/80 mg per ml for Infusion, call your doctor or pharmacist immediately.
- If you have been given too much Co-trimoxazole 16 mg/80 mg per ml for Infusion, call your pharmacist immediately.
- Overdosage:
  - Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
  - Undesirable effects:
    - High levels of potassium in your blood, which can cause abnormal heart rhythms.
    - Red patches on the skin
    - Diaphoreza
    - Feeling sick or vomiting
    - Nausea
    - Difficulty in swallowing
    - Difficulty in breathing

**Precautions for use**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- It is recommended that Co-trimoxazole 16 mg/80 mg per ml for Infusion is used in critically ill patients, there may be no therapeutic alternatives.
- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- The dose you will be given, and the frequency of the dose will depend on:
  - The type of infection you have.
  - The level of illness you are suffering from.
  - Whether you have any other medicines you are taking.

**Special precautions for disposal and other handling**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Proper disposal of this product is the responsibility of the patient or medicine user.

**Package information**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Special precautions for storage:
  - Store below 25°C.

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Full list of excipients:
  - Sodium Metabisulphite (E223) BP
  - Tromethamine USP
  - Propylene Glycol (E1520) Ph Eur

**Legal category**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- professionals only
- Code: A00000

**List of excipients**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Sodium: 1.7 mmoles
- Ethanol (alcohol): 80 m g
- Trimethoprim: 80 mg
- Sulfamethoxazole: 400 mg

**Presentation**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Neutral glass ampoules (5 ml nominal fill volume)

**Marketing authorisation holder**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- AstraZeneca Pharmaceuticals LP

**Healthcare Professional information**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- If you are allergic to sulphonamide medicines. Examples include co-trimoxazole.

**Patient information**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- If you have any questions, your doctor or pharmacist should be able to answer them. If you have any other questions, it may be easier, if you are an older woman, for others to answer your questions. If you have to, it may be easier, if you are an older woman, for others to answer your questions.

**Side effects**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
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**Pharmacological class**

- Co-trimoxazole 16 mg/80 mg per ml for Infusion is useful in critically ill patients, there may be no therapeutic alternatives.
- Trimethoprim Sulfonamide (Co-trimoxazole) (see SPC section 4.8 Undesirable effects)
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 people)

Very Rare (less than 1 in 10,000 people)
• Being sick (vomiting)

Very Rare (less than 1 in 100,000 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)
• 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 your 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
• Problems of balance
• Problems with your speech
• Problems with your vision
• Ringing or other unusual sounds in your ears
• Tingling or numbness in your hands and feet
• Seeing strange or unusual sights (hallucinations)
• Depression
• Loss of appetite
• Muscle pain and/or muscle weakness in HIV patients

If any of the side effects gets serious, or if you notice any side effect 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. 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
40A Lake Drive,
Clipstone Business Campus,
Leicester, LE6 0AB
Germany
Medicinal Information Enquiries
For any Medicinal Information requests about this product, please contact:
3.6 New Milton Rd +441748 828 391 (free phone UK only 0800 087 392)
This leaflet was last revised in December 2016.
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.

Pregnancy
Co-Trimoxazole is not recommended for use in pregnancy.
This leaflet was last revised in December 2016.

Other source of information:
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