Co-Trimoxazole 160 mg/800 mg Forte Tablets

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.

Co-Trimoxazole Forte tablets are indicated in children (>12 to <18 years old) and adults (>18 years old).

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

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).
- You are allergic to sulphonamide medicines. Examples include sulphonylureas (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendroflumethiazide – a water tablet).
- You have severe liver or kidney problems.

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
• You have ever had a problem with your blood causing bruises or bleeding (thrombocytopenia).
• You have been told that you have a rare blood problem called porphyria, which can affect your skin or nervous system.
• Co-T 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-T trimoxazole.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-T trimoxazole:
• If you have severe allergies or asthma.
• Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Co-T trimoxazole appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
• 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 or toxic epidermal necrolysis with the use of Co-T trimoxazole you must not be re-started on Co-T trimoxazole at any time.
• If you develop a rash or these skin symptoms, stop taking Co-T trimoxazole, seek urgent advice from a doctor and tell him that you are taking this medicine.
• If you have been told that you are at risk for a rare blood disorder called porphyria.
• If you have a kidney disease.
• 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-T 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 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-T trimoxazole

Tell your doctor or pharmacist if you are taking, have recently taken or may take any other medicines. This is because Co-T trimoxazole can affect the way some medicines work. Also some other medicines can affect the way Co-T 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.
• Phenyltoin, used to treat epilepsy (fits).
• Medicines used to treat diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas) and repaglinide.
• Rifampicin, an antibiotic.
• 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.
• Methotrexate, a medicine used to treat certain cancers or certain diseases affecting your immune system.
• 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.

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

3. How to take Co-Trimoxazole
Always take this medicine exactly as your doctor 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):

<table>
<thead>
<tr>
<th>Age</th>
<th>Forte tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;18 years old</td>
<td>One tablet in a morning and one tablet in an evening</td>
</tr>
</tbody>
</table>

Children over 12 years (>12 to <18 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:

<table>
<thead>
<tr>
<th>Age</th>
<th>Forte tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;12 to &lt;18 years old</td>
<td>One tablet in a morning and one tablet in an evening</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight</th>
<th>Forte tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;53 kg</td>
<td>1 tablet every 12 hours</td>
</tr>
</tbody>
</table>
Co-Ttrimoxazole should be taken for at least five days.
Make sure that you finish the course of Co-Ttrimoxazole which your doctor has prescribed.

Co-Ttrimoxazole 160 mg/800 mg Forte Tablets are not usually given to children under 12 years old. If they have been given to your child under 12 years please speak to your doctor or pharmacist for more information.

**Special Dose**
The dose of Co-Ttrimoxazole 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-Ttrimoxazole 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-Ttrimoxazole.
- Take blood to test whether the medicine is working properly.

If you take Co-Ttrimoxazole 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-Ttrimoxazole.

If you take more Co-Ttrimoxazole than you should
If you take more Co-Ttrimoxazole 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-Ttrimoxazole you may:
- Feel or be sick.
- Feel dizzy or confused.

**If you forget to take Co-Ttrimoxazole**
- 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-Ttrimoxazole can cause side effects, although not everybody gets them. You may experience the following side effects with this medicine.

Stop taking Co-Ttrimoxazole 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

**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)
  - 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

Not known (frequency cannot be estimated from the available data)
Psychotic disorder (a mental state in which you may lose touch with reality)

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. By reporting side effects, you can help provide more information on the safety of this medicine.
5. **How to store Co-Ttrimoxazole**

   Keep this medicine out of the reach and sight of children.
   Do not store above 25°C.
   Do not take the tablets 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-Ttrimoxazole contains**
   Co-Ttrimoxazole is made up of two different medicines called sulfamethoxazole and trimethoprim. Each Co-Ttrimoxazole 160 mg/800 mg Forte Tablet contains 800 mg sulfamethoxazole and 160 mg trimethoprim.
   The other ingredients of Co-Ttrimoxazole 160 mg/800 mg Forte Tablets are: povidone, sodium starch glycollate, magnesium stearate and docusate sodium.

   **What Co-Ttrimoxazole looks like and contents of the pack**
   Co-Ttrimoxazole 160 mg/800 mg Forte Tablets are white elongated tablets, coded S3 on one side. They are biconvex and are scored along the shorter axis.
   The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
   Co-Ttrimoxazole 160 mg/800 mg Forte Tablets are supplied to you in:
   - a propylene container with a propylene snap fit closure, containing 100 tablets, or
   - a round enamelled tin, containing 2000 tablets, or
   - a PVC/aluminium foil blister pack, containing 5 tablets (sample pack) or 100 tablets.

   **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 March 2018.**

   **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-Ttrimoxazole 160 mg/800 mg Forte Tablets**
   Reference number PL 39699/0035
   This is a service provided by the Royal National Institute of Blind People.