Co-trimoxazole Tablets 80/400mg
(Trimethoprim and Sulfamethoxazole)

1. **What Co-trimoxazole tablets are and what they are used for**
   - Co-trimoxazole tablets are made up of two different medicines called sulfamethoxazole and trimethoprim. Both belong to a group of medicines called sulfonamide antibiotics. They are used to treat infections caused by bacteria. Like all antibiotics, Co-trimoxazole tablets are not effective against viruses.
   - Co-trimoxazole tablets are used against many different types of bacteria. This means that it is only suitable for treating some types of infections.
   - Co-trimoxazole tablets are used for adults and children over 12 years.
   - Co-trimoxazole tablets can be used to treat: pneumonia or POI caused by a bacteria called pneumococcus.
   - Co-trimoxazole tablets can be used to treat: Pneumocystis jiroveci, it is caused by a bacteria called Toxoplasma gondii.
   - Co-trimoxazole tablets can be used to treat: bladder or urinary tract infections (infection with bacteria)
   - Co-trimoxazole tablets can be used to treat: infections such as bronchitis
   - Co-trimoxazole tablets can be used to treat: an infection called meningitis, which can affect the brain

2. **Before you take Co-trimoxazole tablets**
   - You should tell your doctor or pharmacist if you:
     - are allergic to any of the ingredients of Co-trimoxazole tablets or any of the other ingredients of Co-trimoxazole tablets (see sections 4 and 5 for further information)
     - have ever had a rare blood problem called porphyria, or
     - have had problems with your blood
     - have ever had jaundice, it can cause yellowing of your skin or the whites of your eyes
     - have ever had jaundice, it can cause yellowing of your skin or the whites of your eyes
     - have ever been told by your doctor that you have a lot of potassium in your blood
     - have a problem with your metabolism called phenylketonuria and are on a special diet to help your condition
     - are elderly
     - you are underweight or malnourished
     - you have been told by your doctor that you have a lot of potassium in your blood
     - you don't have enough folate, which is a vitamin in your body, which can make your skin pale and make you feel tired, weak and breathless. This is known as anaemia
     - you have ever had jaundice, which can cause yellowing of your skin or the whites of your eyes
     - you have a problem with your metabolism called phenylketonuria and are on a special diet to help your condition
     - you are elderly
     - you are underweight or malnourished
     - you have been told by your doctor that you have a lot of potassium in your blood

3. **How to take Co-trimoxazole tablets**
   - You should take the tablets with or without food. If you have any problems, talk to your doctor or pharmacist.
   - Do not crush or split the tablets, unless instructed to do so by your doctor or pharmacist.
   - Drink plenty of fluid such as water while you are taking Co-trimoxazole tablets.
   - You should take Co-trimoxazole tablets with food and drink if you are taking any other medicines that might affect the way Co-trimoxazole tablets work.
   - You should take Co-trimoxazole tablets with food and drink if you are taking any of the following medicines:
     - Medicines to treat problems with your heart such as digoxin or procainamide
     - Medicines to treat Parkinson’s disease, multiple sclerosis, ‘flu (influenza)
     - Medicines to treat problems with your liver such as lamivudine or zidovudine
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4. **Possible side effects**
   - Side effects are the symptoms of an illness that happen as a result of taking a medicine. Side effects are usually mild and pass on their own.
   - The most common side effects are:
     - An upset stomach, feeling sick or vomiting
     - Diarrhoea
     - Headaches
     - Skin rashes
     - Dizziness
     - Constipation
     - Allergic reactions
   - In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
     - Medicines to treat problems with your liver such as lamivudine or zidovudine
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5. **How to store Co-trimoxazole tablets**
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6. **Further information**
   - Skin reactions - if you develop a rash or any of the following symptoms, seek immediate advice from a doctor and tell them that you are taking this medicine:
     - potentially life-threatening skin rash, Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of Co-trimoxazole appearing initially as reddish target-like spots or circular patches often with central blisters or 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 6 weeks of treatment.
     - If you have developed Stevens-Johnson syndrome, toxic epidermal necrolysis or DRESS with the use of Co-trimoxazole tablets you must not be re-started on Co-trimoxazole tablets at any time.

Taking other medicines
   - Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those bought without prescription. This includes herbal medicines. This is because Co-trimoxazole tablets can affect the way these medicines work. Also some other medicines can affect the way Co-trimoxazole tablets work.
   - In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
     - Sulphonamides, used to treat various infections including respiratory infections such as pneumonia. Other medicines called antibiotics. They are used to treat infections caused by some bacteria. Like all antibiotics, Co-trimoxazole tablets can affect the way some medicines work. Also some other medicines can affect the way Co-trimoxazole tablets work.
     - Sulphonamides, used to treat various infections including respiratory infections such as pneumonia. Other medicines called antibiotics. They are used to treat infections caused by some bacteria. Like all antibiotics, Co-trimoxazole tablets can affect the way some medicines work. Also some other medicines can affect the way Co-trimoxazole tablets work.

Pregnancy and breast-feeding
   - Talk to your doctor before taking this medicine if you are pregnant, planning to get pregnant, or breast-feeding.

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**How to take Co-trimoxazole tablets**

Always take Co-trimoxazole tablets exactly as your doctor has told you. The label on your pack will tell you how much to take and how often to take them. You should check with your doctor or pharmacist if you are not sure.

### Usual Dose

**Adults**
- The usual dose is two tablets in the morning and two tablets in the evening.
- Co-trimoxazole tablets should be taken for at least five days.
- Make sure that you finish the course of Co-trimoxazole tablets which your doctor has prescribed.

**Children over 12 years**

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

<table>
<thead>
<tr>
<th>Age</th>
<th>Usual Dose</th>
</tr>
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<tbody>
<tr>
<td>12 years and over</td>
<td>Two tablets in a morning and two tablets in an evening</td>
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</table>
| OR
| Weighing 51 kg or above | Two tablets in a morning and two tablets in an evening |

### Special Dose

The dose of Co-trimoxazole tablets 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-trimoxazole tablets:

- Treat urinary tract (water) infections: two tablets daily for 7 days.
- Treat and prevent lung infections caused by the bacteria Pneumocystis jiroveci: two tablets daily for 21 days.
- Treat infections caused by the bacteria Toxoplasma gondii or Nocardia asteroides.

If you have kidney problems your doctor may prescribe a lower dose of Co-trimoxazole tablets.

If you take Co-trimoxazole tablets for a long time your doctor may prescribe a different dose or length of course of Co-trimoxazole tablets.

If you take more Co-trimoxazole tablets than you should:

- If you take more Co-trimoxazole tablets 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 many Co-trimoxazole tablets you may:
  - feel sick
  - feel dizzy or confused.

If you forget to take Co-trimoxazole tablets:

- 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.
- If you forget to take Co-trimoxazole tablets:
  - feel dizzy or confused.
  - feel or be sick

If you take more Co-trimoxazole tablets 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 many Co-trimoxazole tablets you may:

- feel sick
- feel dizzy or confused.

If you forget to take Co-trimoxazole tablets:

- 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.
- If you forget to take Co-trimoxazole tablets:
  - feel dizzy or confused.
  - feel or be sick

### Possible side effects

Like all medicines, Co-trimoxazole tablets can cause side-effects, although not everyone gets them. You may experience the following side-effects with this medicine. Stop taking Co-trimoxazole tablets and tell your doctor immediately if you have an allergic reaction. Changes of an allergic reaction are very rare (< 1 in 10,000 people 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)

- An infection called thrush or candidiasis which can affect your mouth or vagina. It is caused by fungi.
- 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 wheezing or difficulty breathing
- Potentially life threatening skin rash (Stevens-Johnson syndrome, toxic epidermal necrolysis) has been reported (see Special care with Co-trimoxazole tablets).
- Mouth ulcers, cold sores and ulcers or sores of your tongue
- Skin rashes (shaped, red or white, itchy patches of skin)
- Itching 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 off balance, pale skin (anaemia)
- Heart problems.

#### Rare

- Jaundice (yellowing of the skin and the whites of your eyes turn yellow). This can occur at the same time as unexpected bleeding or bruising.
- Pins in your stomach, which can occur with blood in your faeces (poo)
- Pins in your chest, muscles or joints and muscle weakness

#### Arthritis

- Problems with your joints.
- Difficulty passing urine. Posing more or less urine than usual, Blood or cloudiness in your urine.
- Kidney problems.

#### Sudden death in your heart, caused by a fungus (Pneumocystis jiroveci) 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

- Drug reaction with eosinophilia and systemic symptoms (DRESS). This can occur up to 1 month after you stop taking Co-trimoxazole tablets.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes:

- Changes of an allergic reaction
- Any other 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 the medicine.

### How to store Co-trimoxazole tablets

Keep out of reach of children, keep in a dry place, protect from light.

### Further information

**What Co-trimoxazole tablets contain**

- The active substances: the ingredients that make the tablets work are 80 mg of trimethoprim and 400 mg of sulfamethoxazole.
- The other ingredients are lactose, corn starch, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate and stearic acid.

**What Co-trimoxazole tablets look like and contents of the pack**

Co-trimoxazole tablets are white, circular, bevrons coated tablets. Pack sizes are 28 tablets.

Marking Authority and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK

This leaflet was last revised in September 2017.