What Co-trimoxazole is and what it is used for

The name of your medicine is Co-Trimoxazole 80/400 mg Tablets or Co-Trimoxazole 160/800 mg Tablets (called Co-trimoxazole in this leaflet) which contains two active substances called trimethoprim and sulphamethoxazole in three strengths:
- Co-Trимoxazole 80/400 mg Tablets (80 mg of Trimethoprim and 400 mg of Sulphamethoxazole)
- Co-Trимoxazole 160/800 mg Tablets (160 mg of Trimethoprim and 800 mg of Sulphamethoxazole)

Both the active substances belong to a group of medicines called antibiotics. Antibiotics are used to treat infections caused by bacteria. Co-trimoxazole works against some types of bacteria, therefore it is only suitable for treating some types of infections.

Co-trimoxazole can be used to treat:
- or prevent lung infections (pneumonia) caused by the bacteria Pneumocystis jirovecii
- or prevent infections such as toxoplasmosis
- bladder or urinary tract infections
- infections of the chest (chronic bronchitis)
- ear infections (otitis media) in children
- infections such as necardiosis (bacterial infection affecting the lungs, skin and brain)

Co-trimoxazole 80/400 mg and 160/800 mg Tablets are used in adults and children over 12 years of age.

You must talk to a doctor if you do not feel better or if you feel worse.

What you need to know before you take Co-trimoxazole

Do not take Co-trimoxazole tablets if:
- you are allergic to trimethoprin, sulphamethoxazole or any other ingredients of this medicine (listed in section 6)
- you have severe liver or kidney problems
- you have or ever had any blood disorder or anaemia or porphyria (a rare blood problem affecting your skin or nervous system)
- you have reduced amount of the enzyme glucose-6-phosphate dehydrogenase (G6PD)

Co-trimoxazole should not be given to infants during the first 6 weeks of life.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-trimoxazole tablets if:
- potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Co-trimoxazole,
- you have a problem with your metabolism called phenylketonuria and are on a special diet.
- you have high potassium levels in blood (hyperkalemia) and close monitoring is necessary.
- you are elderly.

Tests:

Regular blood and urine tests are recommended for patients on long term treatment.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-trimoxazole.

Other medicines and Co-trimoxazole tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. 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:
- medicines to thin the blood (warfarin)
- pyrimethamine, used to treat and prevent malaria
- medicines to treat diabetes (glibenclamide or tolbutamide, repaglinide, rosiglitazone)
- medicines used after organ transplants or for your immune system (cyclosporin, azathioprine)
- medicines used to treat heart failure or heart rhythm problems (digoxin, amiodarone, procainamide)
- medicines used to treat bacterial infections (such as rifampicin and dapson)
- methotrexate, used to treat cancer or for your immune system
- phenytoin, used to treat seizures
- medicines that can increase the amount of potassium in your blood, such as diuretics (water tablets such as spironolactone, amiloride) or angiotensin-converting enzyme inhibitors (enalapril, quinapril)
- medicines to treat HIV or AIDS (lamivudine, zidovudine or didanosine)
- amantadine, used to treat Parkinson’s disease
- clozapine, used to treat mental problems
- lidocaine/prilocaine (in infants)
- loperamide, used to treat diarrhoea

Co-trimoxazole tablets with food and drink

You should take Co-trimoxazole with some food and drink.

This will stop you feeling sick (nausea) or having diarrhoea. Drink plenty of 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.

This medicine should not be used during pregnancy, or when you are breast feeding. Co-trimoxazole is excreted in breast milk causing problems in breast-fed infants.

3. How to take Co-trimoxazole

Always take Co-trimoxazole exactly as your doctor has told you. The label on your pack will tell you how much to take and how often to take it. You should check with your doctor or pharmacist if you are not sure.
The usual dose for acute infections depends on either your age or weight. The recommended dose is:

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Recommended dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 12 years and above including elderly OR Body weight 53 kg or above</td>
<td>960 mg (160 mg trimethoprim and 800 mg sulphamethoxazole) twice daily.</td>
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</tbody>
</table>

Your doctor may prescribed you the dose to treat or prevent lung infections (Pneumonia or PCP). The dose and frequency will depend on:

- the type and severity of infection you have
- your weight
- your age

The doses should be reduced in patients with kidney problems and your doctor shall decide the dose depending on your condition.

If you take more Co-trimoxazole tablets than you should
If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include vomiting, blurred vision, confusion, skin discolouration or jaundice.

If you forget to take Co-trimoxazole tablets
If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Co-trimoxazole tablets
Do not stop taking Co-trimoxazole tablets because you feel better. Take the tablets for as long as your doctor has told you or your problem may come back.

4. Possible side effects

Like all medicines, Co-trimoxazole tablets can cause side-effects, although not everybody gets them.

Stop taking the tablets immediately and seek urgent medical advice if the following occur:

- allergic reactions: skin rashes which may be itchy, skin flushing, swelling of the face, lips, tongue or throat, difficulty breathing, extreme tiredness, joint stiffness, fever, wheezing, abdominal pain, feeling or being sick.
- inflamed heart muscle (chest pain, fever, a fast heartbeat, tiredness), systemic lupus erythematosus (SLE-skin rash, hair loss, difficulty breathing and joint pains).
- aseptic meningitis (headache, fever, stiff neck, tiredness, feeling ill and sensitivity of eyes to bright light).
- Very rare, potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).

Tell your doctor if the following side effects occur:

- effects on blood: changes in the numbers and types of your blood cells. If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test.
- feeling or being sick, diarrhoea, inflammation of tongue/intestines (difficulty in swallowing, swelling or ulceration of the gut), inflammation of the pancreas (abdominal pain, being sick, fever unwell); pseudomembranous colitis (causing severe and painful diarrhoea).
- loss of appetite, decreased levels of sodium, low blood glucose, increased levels of potassium (hyperkalaemia).
- Muscle/joint pain or muscle weakness.
- liver failure or jaundice (yellowing of the skin or whites of the eyes), changes in levels of liver enzymes.
- kidney problems, abdominal pain, difficulty passing urine, blood in urine, crystals in the urine (this can be avoided by drinking plenty of water).
- headache, depression, dizziness, seeing strange or unusual sights (hallucinations), fits, lack of co-ordination (ataxia), drowsiness.

- other effects: cough, shortness of breath, swollen skin (angioedema), sensitivity to light, painful red eyes with blurred vision (uveitis), inflammation of blood vessels, colour change of skin (pupura), spitting sensation, ringing in the ears, fungal infections (thrush).

Most commonly, high frequency of side effects are reported in elderly patients.

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.

Do not use this medicine after the expiry date (EXP.) which is stated on the label or carton.

Do not store above 25°C. Store it in a dry place, in well-closed container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Co-trimoxazole tablets contain
Co-trimoxazole tablet contains the active ingredients, trimethoprim and sulphamethoxazole.

- 80/400 mg tablets: 80 mg of trimethoprim and 400 mg of sulphamethoxazole.
- 160/800 mg tablets: 160 mg of trimethoprim and 800 mg of sulphamethoxazole.

The 80/400 mg tablets and 160/800 mg tablets contain povidone K25, crospovidone and magnesium stearate.

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

- 80/400 mg tablets: Flat, white, bevelled tablets, engraved ‘80’ and ‘400’ on the scored side.
- 160/800 mg tablets: White, capsule shaped tablets, engraved ‘160’ and ‘800’ on the scored side.

80/400 mg tablets are available in containers of 100, 500 tablets and in blisters of 10, 28, 30 tablets. 160/800 mg tablets are available in containers of 100 tablets.

Not all pack sizes may be marketed.

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For any information about this medicine, please contact the Marketing Authorisation Holder.

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