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

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

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1. What Co-trimoxazole tablets are and what they are used for
Co-trimoxazole 80mg/400mg Tablets (called 'Co-trimoxazole tablets' in the leaflet) are made up of two different medicines called sulfamethoxazole and trimethoprim. Both belong to a group of medicines called sulfonylureas. They are used to treat infections caused by bacteria. Like all antibiotics, Co-trimoxazole only works against some types of bacteria. This means that it's only suitable for treating some types of infections.

Co-trimoxazole tablets can be used to treat or prevent:
- Lung infections (pneumonia or PCP) caused by a bacteria called Pneumocystis (previously known as Pneumocystis carinii)
- Infections caused by a bacteria called Toxoplasma (toxoplasmosis).

Co-trimoxazole tablets can be used to treat:
- Bladder or urinary tract infections (water infections)
- Lung infections such as bronchitis
- Ear infections such as otitis media
- An infection called gonorrhoea, it can affect the lungs, skin and brain.

2. Before you take Co-trimoxazole tablets
Do not take Co-trimoxazole tablets if:
- You are allergic (hypersensitive) to sulfamethoxazole, trimethoprim or Co-trimoxazole or any of the other ingredients of Co-trimoxazole tablets (see section 6 Further information)
- You are allergic to sulfonamide medicines. Examples include sulfonylurans (such as gliclazide and glibenclamide) or thiazide diuretics (such as bendrofluamide - a water tablet)
- You have liver or kidney problems
- You have ever had a problem with your blood
- It's for your child and they are less than 6 weeks old or were premature. Unless it's for the treatment or prevention of PCP. In this case, babies should be at least 4 weeks old.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-trimoxazole tablets.

Take special care with Co-trimoxazole tablets
- You have ever had allergies or asthma
- You have been told that you have a rare blood disease called porphyria, which can affect your skin or nervous system
- 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
- 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 not 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.

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

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 rashes (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 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, 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 medicines obtained without a prescription. This includes herbal medicines. This is because Co-trimoxazole tablets can affect the way some 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:
- Diuretics (water tablets), which help increase the amount of urine you produce
- Pimobendan, used to treat heart failure, and to treat heart failure
- Cyclosporin, used after transplant operations or for your immune system
- Medicines used to treat the blood such as warfarin
- Phenytion, used to treat epilepsy (fits)
- Medicines for diabetes, such as gliclazide, glipizide or tolbutamide (sulfonylurans)
- 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, steroids (like prednisolone) and digoxin
- Methotrexate, a medicine used to treat cancer or for your immune system. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-trimoxazole tablets.

Taking Co-trimoxazole tablets with food and drink
You should take Co-trimoxazole tablets with some food or drink. This will stop you feeling sick (nausea) or having diarrhoea.

Although it is better to take them with food, you can still take them on an empty stomach. Drinking plenty of fluid such as water while you are taking Co-trimoxazole tablets.
Pregnancy and breast-feeding

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

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 and children over 12 years

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

Co-trimoxazole tablets are not usually given to children under 12 years old. If they have been given to your child please speak to your doctor or pharmacist for more information.

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 a different dose or length of course of Co-trimoxazole to:
• treat urinary tract (water) infections
• treat and prevent light infections caused by the bacteria Pneumocystis jiroveci
• treat infections caused by the bacteria Toxoplasma gondii or Nocardia (nocardiosis).

If you have kidney problems your doctor may
• prescribe a lower dose of Co-trimoxazole tablets
• take blood to test whether the medicine is working properly.

If you take Co-trimoxazole tablets 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-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 or be 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.

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

You may experience the following side effects with this medicine.

Stop taking Co-trimoxazole tablets and tell your doctor immediately if you

• feel or be sick
• take blood to test whether the medicine is working properly.

• prescribe a lower dose of Co-trimoxazole tablets
• 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-trimoxazole tablets.

Possible side effects

Take all medicines, Co-trimoxazole tablets can cause side-effects, although not everybody 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 is very rare (fewer than 1 in 10,000 people are affected), signs of an allergic reaction include:

• Difficulty in breathing
• Swelling of the face, tongue or throat which may be red and painful
• Difficulty in swallowing
• Chest pain
• Red patches on the skin.

Common (more than 1 in 10 people)

• High levels of potassium in your blood, which can cause abnormal heart beats (palpatations).

Common (less than 1 in 10 people)

• An injection called thush or candidiasis which can affect your mouth or vagina. It is caused by a fungus
• Headache
• Feeling sick (nausea)
• Diarrhoea
• Skin rashes.

Uncommon (less than 1 in 100)

• Being sick (vomiting).

Unlikely to occur (less than 1 in 1,000 people)

• Ear problems
• Changes in blood tests
• Low levels of sodium in your blood
• Problems with your urine. Difficulty passing urine. Passing more or less urine than usual. Blood or cloudiness in your urine.
• Kidney problems
• Tongue
• Difficulty breathing.

Very Rare (less than 1 in 10,000 people)

• Fever (high temperature) or frequent infections
• Sudden wheezing or difficulty breathing
• Potentially life-threatening skin rashes (Stevens–Johnson syndrome, toxic epidermal necrolysis) have been reported (see Take special care with Co-trimoxazole tablets).
• Mouth ulcers, cold sores and ulcers or soresness of your tongue
• Skin rashes or hives (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 eye turn yellowish). This can occur at the same time as unexpected bleeding or bruising
• Pains in your stomach, which can occur with blood in your faeces (poop)
• 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)
• Muscle pain and/or muscle weakness in HIV patients
• Loss of appetite
• Gout.

Not Known

• Drug reaction with eosinophilia and systemic symptoms (DRESS)

Reporting of side effects

If you get any side-effects, talk to your doctor, pharmacist or nurse. 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.

Technical Approval

This leaflet was last revised in January 2016.

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