PATIENT INFORMATION LEAFLET

CO-TRIMOXAZOLE 20/100 MG TABLETS

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE

What is in your medicine?

The name of this medicine is Co-Trimoxazole 20/100 mg Tablets which contains a combination of 20mg Trimethoprim and 100mg Sulphamethoxazole.

Co-Trimoxazole 20/100 mg tablets also contain povidone, crospovidone, magnesium stearate and microcrystalline cellulose.

Co-Trimoxazole 20/100 mg Tablets are available in containers of 100 tablets.

How does* Co-Trimoxazole *work?

Co-Trimoxazole is an antibacterial drug which is helpful in the prevention and treatment of bacterial infections sensitive to Co-Trimoxazole, affecting the lungs and genito-urinary tract. It is also used for treatment of middle ear inflammation in children.

If you are not sure why you have been prescribed Co-Trimoxazole then please ask your doctor.

The Manufacturer is: DDSA Pharmaceuticals Ltd., Chatfield Road, off York Road, London SW11 3SE.

The Product Licence Holder of Co-Trimoxazole 20/100 mg Tablets is: Activase Pharmaceuticals Limited, Boumpoulinas 11, 3rd Floor, Nicosia, P.C. 1060, Cyprus

What are* Co-Trimoxazole *tablets for?

Co-Trimoxazole tablets are used for the prevention and treatment of inflammation of the lungs in adults and children, and for the treatment of urinary tract infections, and for acute attacks of bronchitis in patients who suffer from chronic bronchitis.
Co-Trimoxazole is also used for the treatment of middle ear inflammation in children.

Check before you take these tablets

Before taking this medicine, tell your doctor if you have ever had any unusual or allergic reactions to Sulphamethoxazole or Trimethoprim, or any of the other ingredients of Co-Trimoxazole, or other sulphonamide medicines or medicines used in the treatment of diabetes.

Also tell your doctor or pharmacist if you are allergic to any other substances such as foods, preservatives or dyes. Also tell them if you are taking any medicines known as blood thinners, any antimalarial drugs (particularly pyrimethamine), or medicines for the treatment of diabetes such as tolbutamide or glibenclamide.

It is important that you tell your doctor if you are pregnant, or likely to become pregnant, or if you are breast feeding.

If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately

Haemophagocytic lymphohistiocytosis
There have been very rare reports about excessive immune reactions due to a dysregulated activation of white blood cells resulting in inflammations (haemophagocytic lymphohistiocytosis), which can be life-threatening if not diagnosed and treated early. If you experience multiple symptoms such as fever, swollen glands, feeling weak, lightheaded, shortness of breath, bruising, or skin rash simultaneously or with a slight delay, contact your doctor immediately.

Pregnancy

This medicine should not be used during pregnancy, or when you are breast feeding.

Can you take* Co-Trimoxazole *with other medicines?

You can take these tablets with other medicines, but there are some medicines that can interfere with Co-Trimoxazole tablets.

It is very important to tell your doctor or pharmacist about all the medicines which you are taking, whether prescribed by your doctor or bought without a prescription from the pharmacy or elsewhere. This includes medicines such as antimalarials (particularly pyrimethamine), medicines for the treatment of diabetes such as tolbutamide and glibenclamide and medicines used as blood thinners. Medicines used for Rheumatoid arthritis such as Cyclosporin; medicines used for heart problems such as Digoxin; medicines used for tuberculosis, such as Rifampicin.

The presence of other medical problems may affect the use of this medicine. Make sure, therefore, to tell your doctor or pharmacist if you have other medical problems such as liver problems, kidney problems, anaemia, diabetes, lung disease, malaria, infection of the urinary tract (including sexually transmitted diseases such as gonorrhoea).

Also tell your doctor or pharmacist is you are taking drugs known as sulphonamides.

When and how to take* Co-Trimoxazole *tablets.

Co-Trimoxazole tablets are taken by mouth and only in the doses prescribed by your doctor. Do not take more of them, and do not take them more often or for a longer time than your doctor ordered.

Do not stop taking your medicine or change the dose unless your doctor tells you to.

You will be prescribed the lowest dose necessary to control your symptoms.

Dosages

Adults and children over 12 years:
2 Co-Trimoxazole tablets (or one Co-Trimoxazole 160/800 mg tablet) twice daily.

For treatment exceeding 14 days and for a minimum dosage 1 Co-Trimoxazole tablet (or ½ a Co-Trimoxazole 160/800 mg tablet) twice daily.

In severe infections and for septicaemia (infection in the blood stream) 3 Co-Trimoxazole 80/400 mg tablets (or 1½ Co-Trimoxazole 160/800 mg tablets) twice daily.

For gonorrhoeal infections (uncomplicated) 4 Co-Trimoxazole tablets (or 2 Co-Trimoxazole 160/800 mg tablets) 12 hourly during a 48 hour period (over 2 days).

Children (6 to 12 years): 1 Co-Trimoxazole tablet twice daily (or 4 Co-Trimoxazole 20/100 mg tablets twice daily)

Children (2 to 5 years): 2 Co-Trimoxazole 20/100 mg tablets twice daily.

Elderly: Treatment should commence with one Co-Trimoxazole tablet twice daily and increased, if necessary, to the adult dosage.

Treatment in all acute infections should be continued for a minimum of 5 days or until you are symptom-free for two days or whichever is the longer.

What to do if too many tablets are taken at the same time.

If you accidentally take more tablets than recommended, contact your doctor or local hospital Casualty Department at once.
What if you miss a dose?

If you miss a dose, skip the missed dose and go back to your regular dosage schedule. Do not double the dose.

If you feel that this medicine is not working as well after you have taken it for a short time, do not increase the dose, instead check with your doctor.

What side effects can* Co-Trimoxazole *have?

Call the emergency department immediately if you experience multiple symptoms such as fever, very low blood pressure or increased heart rate after taking this drug as it may be a sign of shock.

Co-Trimoxazole can cause various blood disorders, and the elderly are most susceptible to these disorders of the blood. If you notice a sore throat, fever and bruising tell your doctor immediately.A blood count should be measured if treatment is continued for 4 weeks or longer.
Side-effects include: skin rashes and sensitivity to light. Occasionally, serious skin reactions can develop. If changes start to affect your skin, contact a doctor immediately.

Allergic reactions may occur, rarely fluid under the skin and mucous membranes, allergic shock and allergic inflammation of the heart and of the arteries.
In patients with a condition known as glucose-6-phosphate dehydrogenase deficiency, a destruction of blood cells may occur.
Increased secretions of the liver such as bilirubin (bile) and rarely jaundice and liver poisoning.
A feeling of sickness, vomiting, diarrhoea, inflammation of the tongue and mouth and loss of appetite.
Non-infectious meningitis which returns to normal when the drug is withdrawn, convulsions.

Inflammation of the nerves of the arms and legs, walking difficulty (ataxia), dizziness and a spinning sensation, ringing noises in the ears (tinnitus), headache, depression, hallucinations.
Kidney function may be reduced with rarely inflammation of the kidney.

Cough, difficulty in breathing.
Increase of potassium in the blood and a decrease of sodium in the blood.
Painful joints and muscles.

Most people do not develop serious side effects. However, should any of the above occur or if you notice any other problems, report to your doctor.

Storing your medicine

You must keep the medicine in a safe place where children cannot get it. Your medicine could harm them.

Keep your medicine in a dry place, below 25°C in a well-closed container.

If your doctor tells you to stop the treatment, return any remaining tablets to the pharmacist. Only keep the medicine if the doctor tells you to.

On the label you will find the words "Expiry Date" followed by numbers indicating the day, month and year. This is the date when the medicine is no longer fit for use. Do not use the medicine after this date, but return it to your doctor or pharmacist.

A reminder

REMEMBER this medicine is for you. Never give it to someone else, even if their symptoms are the same as yours.

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

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