

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

COTRIKANT 480

Co-trimoxazole Tablets BP 480 mg

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

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1. What Cotrikant 480 are and what they are used for

The name of your medicine is COTRIKANT 480 Tablets.

COTRIKANT 480 is a combination of two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by certain bacteria. Like all antibiotics, Co-Trimoxazole only works against some types of bacteria. This means that it is only suitable for treating some types of infections.

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 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 COTRIKANT 480

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 severe kidney problems.
- 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-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-Trimoxazole.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-Trimoxazole:

- If you have severe allergies or asthma.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms) have been reported with the use of Co-Trimoxazole appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.
- At the start of treatment, the occurrence of a generalised skin redness with pustules, accompanied by fever, should raise the suspicion of a serious reaction called generalised acute exanthematous pustulosis (AGEP) (see section 4).
- 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 drug reaction with eosinophilia and systemic symptoms with the use of Co-Trimoxazole you must not be re-started on Co-Trimoxazole at any time.
- If you develop a rash or these skin symptoms, stop taking Co-Trimoxazole, seek urgent advice from a doctor and tell him that you are taking this medicine.
- 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.

- If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately.
- If you have been told that you are at risk for a rare blood disorder called porphyria.
- 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 have a kidney disease.

- 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).
- 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-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.

Other medicines and Co-Trimoxazole

Tell your doctor or pharmacist if you are taking, have recently taken or may take any other medicines. 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:

- 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.
- Phenytoin, 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), digoxin or ACE inhibitors (may be used to treat high blood pressure or some heart problems).
- Azathioprine, may be used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease.
- Methotrexate, a medicine used to treat certain cancers or certain diseases affecting your immune system.
- Folic 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 COTRIKANT 480

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):

STANDARD DOSAGE

Age Tablets

>18 years old 2 tablets every 12 hours

Children over 12 years old (>12 to <18 years old):

The standard dosage for children is equivalent to approximately 6 mg trimethoprim and 30 mg sulfamethoxazole per kg body weight per day, given in two equally divided doses. The schedules for children are according to the child's age and weight and provided in the table below:

Age Tablets

>12 to <18 years old 2 tablets every 12 hours

Body weight Tablets

>27 kg 1 tablet every 12 hours

>53 kg 2 tablets every 12 hours

- Co-Trimoxazole should be taken for at least five days.
- Make sure that you finish the course of Co-Trimoxazole which your doctor has prescribed.

Co-Trimoxazole 80 mg/400 mg 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-Trimoxazole 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 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-Trimoxazole.
- Take blood to test whether the medicine is working properly.

If you take Co-Trimoxazole 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.

If you take more Co-Trimoxazole than you should

If you take more Co-Trimoxazole 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-Trimoxazole you may:

- Feel or be sick.
- Feel dizzy or confused.

If you forget to take Co-Trimoxazole

- 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-Trimoxazole can cause side effects, although not everybody gets them. You may experience the following side effects with this medicine.

Stop taking Co-Trimoxazole 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)
- Very rare cases of redness generalising to the whole body (generalised acute exanthematous pustulosis (AGEP)) (see section 2).
- 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)
- Plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweets syndrome)
 - Drug reaction with eosinophilia and systemic symptoms (an allergic type reaction in which you may develop fever, skin rash, and abnormalities in blood and liver function tests (these may be signs of a multi-organ sensitivity disorder)).

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE COTRIKANT 480

Store in a dry place below 30°C. Protect from light.

Keep all medicines away from children.

Do not use these tablets after the expiry date shown on the blister/label. The expiry date refers to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Co-Trimoxazole is made up of two different medicines called sulfamethoxazole and trimethoprim.

Each Co-Trimoxazole 80 mg/400 mg Tablet contains 400 mg sulfamethoxazole and 80 mg trimethoprim.

The other ingredients of Co-Trimoxazole 80 mg/400 mg Tablets are: Maize Starch , Docusate Sodium, Purified Talc, Sodium Starch Glycolate, Magnesium Stearate

What COTRIKANT 480 looks like and contents of the pack:

COTRIKANT 480 are White coloured, circular flat faced beveled edge ,uncoated tablet having central breakline on one side with COTRI & 480 debossed on it and other side plain.

10 tablets in Alu- PVC blister pack .Such 10 blisters are further packed in a carton along with insert.

- **Supplier and Manufacturer**



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