TRIMETHOPRIM Tablets 100mg & 200mg

Please read all of this leaflet carefully before you start taking this medicine.

Keep the leaflet; you may need to read it again. If you have any questions or are not sure about anything, 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 Trimethoprim Tablets are and what they are used for

Trimethoprim belongs to a group of medicines known as anti-bacterials which are effective against a wide range of bacteria. This medicine is used to treat infections of the urinary tract and chest infections (such as bronchitis and pneumonia) and in the prevention of urinary tract infections in patients with a tendency to recurrent infections.

2. Before you take Trimethoprim Tablets

Do not take these tablets if:

- you are allergic to Trimethoprim or to any of the other ingredients (see section 6)
- · you have severe kidney disease
- · you have a blood problem/disorder
- · you are pregnant, think you may be pregnant or are breast feeding.

This medicine should not be given to premature babies or babies under 2 months old.

Check with your doctor before taking these tablets if:

- you have porphyria
- · you have kidney problems
- you are taking or have in the past taken folic acid supplements or if you have anaemia. Your doctor may want you to take
 a folic acid supplement whilst you are taking this medicine.

Taking other medicines

Check with your doctor or pharmacist before taking these tablets if you are taking any other medicines, including any that you can buy without a prescription. This is especially important if you are taking:

- pyrimethamine (used for the treatment of malaria)
- warfarin or acenocoumarol (to prevent blood clotting)
- phenytoin (to treat epilepsy)
- rifampicin or dapsone (antibacterials)
- procainamide or digoxin (used to treat heart conditions)
- ciclosporin or azathioprine (used to prevent rejection after an organ or tissue transplant and other conditions such as inflammatory bowel disease or rheumatoid arthritis)
- methotrexate or mercaptopurine (used to treat some cancers or rheumatoid arthritis)
- lamivudine or zalcitabine (used to treat HIV infection)
- drugs which depress bone marrow e.g. some cancer treatments.

Other special warnings:

It is important that your doctor checks your progress at regular visits if you are taking this medicine for a long time or if you have kidney disease. Your doctor may carry out regular blood tests.

Pregnancy and breast feeding:

Do not take this medicine if you are pregnant, think you may be pregnant, or you are breast feeding.

Driving and using machinery:

This medicine should not affect your ability to drive or to operate machinery. However, if you think you are affected do not drive or operate machinery.

Important information about an ingredient of Trimethoprim Tablets:

Contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Trimethoprim Tablets

Swallow the tablets with a drink of water.

Your doctor will decide the dose that is best for you. The pharmacist's label will tell you how many tablets to take and how often to take them. If you are not sure about anything, ask your doctor or pharmacist. Typical doses are given below.

Urinary tract and chest infections:

Treatment is usually for between 3 -14 days. Your doctor may double your first dose.

Adults and children over 12 years: One 200mg tablet twice daily or two 100mg tablets twice daily.

Children aged 6-12 years: One 100mg tablet twice a day.

Long term treatment and prevention of recurrent infections:

Adults and children over 12 years: One 100mg tablet at night.

Children aged 6-12 years: 50mg at night. The dose determined by the doctor will depend on the child's bodyweight.

Elderly: If you have kidney problems your doctor may decide to give you a lower dose than the usual adult dose above.

Children under 6 years:

Not recommended; a more suitable dosage form of medicine should be used e.g. a liquid preparation.

Keep taking this medicine for as long as your doctor tells you to. Do not stop taking it just because you start to feel better or your problem may reoccur or get worse.

If you have taken too many tablets:

Contact your doctor straight away or go to the nearest hospital casualty department. Take with you any remaining tablets and the pack so that the medicine can be identified.

If you forget to take a dose:

Take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and continue with your normal dosing schedule. DO NOT DOUBLE THE DOSES.

4. Possible side effects

Some people may have side-effects when taking this medicine. If you have any unwanted side-effects you should seek advice from your doctor, pharmacist or other healthcare professional. Also you can help to make sure medicines remain as safe as possible by reporting any unwanted side-effects via the internet at www.mhra.gov.uk/yellowcard alternatively you can call Freephone 0808 100 3352 (available between 10am-2pm Monday - Friday) or fill in a paper form available from your local pharmacy.

If any of the following occur STOP TAKING the tablets IMMEDIATELY and seek medical help, as these may be signs of a serious allergic reaction or skin reaction:

- sudden wheeziness or difficulty breathing or dizziness
- · swelling of the eyelids, face, lips or throat
- blistering of the skin, mouth, eyes or genitals or skin peeling
- · raised itchy, red lumps on the skin (hives), skin rash or itching, skin sensitivity to light
- fever, headache, stiff neck and back, feeling sick, skin rash, eyes being very sensitive to bright light (these may be signs
 of aseptic meningitis).

If you notice any of the following effects tell your doctor or seek medical attention STRAIGHT AWAY:

- · inflammation, rash and flaking of the skin
- fever, sore throat, rash, mouth ulcers, purple patches on the skin, unusual bruising or bleeding (these may be signs of a blood disorder and may be more likely in patients taking this medicine long term)
- · abnormal heart rhythm (beat) which may be caused by high levels of potassium in the blood
- · yellowing of the skin or whites of the eyes, loss of appetite, stomach discomfort, pale stools and dark urine.

Other side effects include:

- · feeling or being sick, abdominal discomfort, swollen tongue, sore mouth
- · muscle pain
- · changes in liver enzymes, increase in blood creatinine and urea nitrogen levels (seen in tests)
- · fever, headache.

5. How to store Trimethoprim Tablets

Keep this medicine in the pack provided and protect from heat, light and moisture.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN

Do not take the tablets if the expiry date on the pack has passed. If you have any medicines that are out of date, return them to your pharmacist for safe disposal.

6. Further information

Ingredients:

Trimethoprim Tablets come in two strengths and contain either 100mg or 200mg of Trimethoprim as the active ingredient. They also contain the following other ingredients: lactose, maize starch, pregelatinised maize starch, magnesium stearate and sodium starch glycolate.

What the medicine looks like:

Trimethoprim Tablets 100mg are white, round, engraved on one side with the company logo and with a breakline and A307 on the other side. Trimethoprim Tablets 200mg are white, round, engraved on one side with the company logo and with a breakline and A322 on the other side.

The medicine is available in pack sizes of 9, 10, 14, 15, 20, 21, 28, 30, 50, 56, 84, 100, 250, 500 & 1000 tablets. (Not all pack sizes may be marketed).

Who makes this medicine and holds the Product Licence:

Crescent Pharma Limited, Units 3 & 4, Quidhampton Business Units, Polhampton Lane, Overton, Hants, RG25 3ED

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