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PACKAGE LEAFLET: Information for the user

Trimethoprim 200mg Tablets

Trimethoprim

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Trimethoprim 200mg Tablets are and what it is used for

Trimethoprim belongs to a group of medicines called anti-infectives: it is a broad spectrum agent which kills a wide range of bacteria causing your symptoms.

Trimethoprim is used for the treatment of wide range of infections caused by organisms that are susceptible to Trimethoprim and particularly for the long term prevention of recurring urinary tract infection.

2. What you need to know before you take Trimethoprim 200mg Tablets

Do not take Trimethoprim 200mg Tablets and tell your doctor if you:

- are allergic (hypersensitive) to trimethoprim or any of the other ingredients of this medicine (listed in section 6).
- have any **blood disorder**
- are **pregnant**
- have **severe liver disease**
- Trimethoprim should not be given to **premature babies** or babies during the first few weeks of life.

Warnings and precautions

Talk to your doctor or pharmacist before taking Trimethoprim 200mg Tablets if you have:

- **kidney** disease or are having **dialysis treatment**
- a **deficiency of folic acid** (may cause anaemia).

Trimethoprim can increase potassium blood levels. Patients at risk of increased potassium blood levels include those with kidney problems, poorly controlled diabetes, or those on certain medicines or potassium supplements. The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache. Your doctor may perform blood tests to monitor your potassium blood levels.

Other medicines and Trimethoprim 200mg Tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your doctor if you are taking any of the following:

- Antibiotics such as rifampicin
- Anticoagulants to prevent your blood clotting such as warfarin
- Ciclosporin (to prevent rejection after transplantation)
- Digoxin (to treat heart conditions)
- Phenytoin (to treat epilepsy)
- Pyrimethamine or dapsone (to treat malaria)
- Immunosuppressant drugs - used in cancer treatment (e.g. methotrexate) or to treat organ rejection after transplant (e.g. azathioprine or ciclosporin)
- Bone marrow depressants.
- Potassium supplements
- Medicines known as ACE inhibitors and angiotensin II antagonists (used to treat high blood pressure and certain heart conditions)
- Heparin (used to treat and prevent blood clots)
- Repaglinide (to treat diabetes)
- Diuretics (water tablets such as eplerenone, spironolactone, amiloride or triamterene)
- Procainamide, to treat abnormal heart rhythm.

Check with your doctor before taking any such medicine while you are taking trimethoprim.

Trimethoprim 200mg Tablets with food and drink

There are no special instructions for taking Trimethoprim 200mg Tablets with food and drink.

Pregnancy and breast-feeding

Trimethoprim should not be used in pregnancy. If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

Sugar Intolerance

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine; as it contains a type of sugar called lactose.

Driving and using machines

There are no known effects on driving ability or using machines.

Blood tests

If you are having treatment over a long time, your doctor may carry out regular blood tests.

Important information about some of the ingredients of Trimethoprim 200mg Tablets

Patients who are intolerant to lactose should note that each Trimethoprim 200mg Tablet contains a small amount of lactose.

3. How to take Trimethoprim 200mg Tablets

Always take Trimethoprim 200mg Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take this medicine by mouth and only in the doses prescribed by your doctor.

- The recommended dose is:

- Severe or sudden infections: (e.g. uncomplicated bacterial cystitis in women) treatment will usually be between 3-14 days, according to the type and severity of infection.

Your doctor may double your first dose.

- Adults and children over 12 years: 200mg twice a day.
- Children 6-12 years: 100mg twice a day.
- Children under 6 years: Not recommended; a more suitable dosage form should be used in this age group.
- Long-term treatment and prevention therapy:
 - Adults and children over 12 years: 100mg at night.
 - Children 6-12 years: 50mg at night. The usual dose is around 2mg per kg body weight of the child per day.
 - Elderly: doses may be reduced in elderly patients, according to kidney function.

If you take more Trimethoprim 200mg Tablets than you should

If you should accidentally swallow a greater quantity of Trimethoprim 200mg Tablets that have been prescribed for you, contact your doctor or the Accident & Emergency Department of your nearest hospital at once. Always keep any remaining tablets in the labelled container in which they were given to you so that the medicine can be identified by the doctor or the pharmacist at the hospital.

If you forget to take Trimethoprim 200mg Tablets

If you forget to take your medicine, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose. If you are not sure, ask your doctor or pharmacist for advice.

If you stop taking Trimethoprim 200mg Tablets.

Do not stop the treatment without talking to your doctor first. You may feel well but the tablets are helping to prevent another attack of your disease. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Trimethoprim 200mg Tablets can cause side effects, although not everybody gets them. Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

STOP taking this medicine and contact your doctor or go to your nearest hospital casualty department IMMEDIATELY if you notice any of the following symptoms:

- Difficulty breathing, swelling of the face, lips, tongue or throat, .
- Chest pain, shock, fainting or collapse
- Blistering/peeling of the skin, skin eruptions/lesions, deep swelling of the skin (angioedema)
- Pancreatitis (signs may include a sudden, severe upper abdominal pain)

Tell your doctor or pharmacist if you notice any of the following side effects:

Very Common (may affect more than 1 in 10 people)

- high levels of potassium in the blood (may result in abnormal heart rhythm)

Common (may affect up to 1 in 10 people)

- feeling and being sick, diarrhoea
- headache
- skin rashes, urticaria
- anaemia (may cause you to feel tired and look pale), sore throats or mouth ulcers (due to a decrease in white blood cells), thrush

Very rare (may affect up to 1 in 10,000 people)

- constipation, severe watery/bloody diarrhoea
- cough
- agitation, abnormal behaviour
- aseptic meningitis can occur in some patients. This may show as a combination of symptoms such as headache, fever, stiff neck, tiredness, feeling ill and your eyes become very sensitive to bright light
- kidney problems (signs may include painful urination or blood in the urine)

- dizziness, tiredness
- convulsions, involuntary movements, pins and needles, shakiness, tremors
- ringing in the ears, vertigo
- eye redness and pain
- increased sensitivity of the skin to the sun
- low blood sugar, low levels of sodium in the blood (may cause nausea, tiredness, muscle cramping)
- anorexia
- depression, anxiety, sleeping difficulties and nightmares, confusion, hallucinations
- jaundice (yellowing of the skin or whites of the eyes), elevation of serum transaminases, (an indication of liver damage), elevation of bilirubin levels
- joint and muscle ache
- shortness of breath, wheezing, nosebleeds
- meningitis (signs may include stiff neck, fever and vomiting)
- lupus erythematosus (an auto-immune disorder)
- purple discolorations of the skin
- fever
- reduction in numbers of blood cells, anaemia

Unknown (frequency cannot be estimated)

- sore tongue and mouth, gastrointestinal disturbances
- pruritus (itching)
- elevation of serum creatinine and blood urea nitrogen levels

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 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 Trimethoprim 200mg Tablets

Keep out of the sight and reach of children.

Store below 25°C in a dry place.

Do not use this medicine after the expiry date which is stated on the carton after EXP DATE. The expiry date refers to the last day of that month.

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 Trimethoprim 200mg Tablets contains

The active substance is Trimethoprim.

The other ingredients are Lactose monohydrate, Povidone K-25, Crospovidone. Sodium starch glycolate (Type A) and Magnesium stearate.

What Trimethoprim 200mg Tablets looks like and contents of the pack

Trimethoprim 200mg Tablets are white, flat bevelled edged tablets, engraved with 'MT200'. The tablets are available in container pack sizes of 50, 100, 500, 1000 and 5000. The tablets are also available in blister packs of 6, 14 and 28 tablets.

Marketing Authorisation Holder and Manufacturer

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