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Package Leaflet: Information for the user

Trimethoprim 100mg Tablets
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 signs of illness are the same as yours.
- If you get any 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:

1. What Trimethoprim Tablets are and what they are used for
2. What you need to know before you take Trimethoprim Tablets
3. How to take Trimethoprim Tablets
4. Possible side effects
5. How to store Trimethoprim Tablets
6. Contents of the pack and other information

1. What Trimethoprim tablets are and what they are used for

Trimethoprim is a type of antibacterial medicine which works by killing bacteria.
Trimethoprim tablets may be used:
- to treat a wide range of infections including urinary infections and respiratory tract infections.
- for long-term prevention of recurrent urinary tract infections.

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

Do not take Trimethoprim Tablets if you
- are allergic (hypersensitive) to trimethoprim or any of the other ingredients of this medicine (listed in section 6)
- are **pregnant** (first 3 months) or might be pregnant
- suffer from any **blood disorders** such as anaemia.
- suffer from severe **liver** problems
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking trimethoprim.

Trimethoprim should not be administered to premature babies or infants under 4 months of age.
The tablet form is NOT recommended for use in children under 6 years - the oral liquid form should be used.

Warnings and Precautions
Talk to your doctor or pharmacist before taking Trimethoprim tablets if you:
- are pregnant
- suffer from kidney problems/kidney disease or are having dialysis treatment.
- have a deficiency (are low) in folic acid (may cause anaemia)
- are at greater risk of high levels of potassium in your blood (hyperkalaemia), e.g. the elderly or those on higher doses
- are also taking repaglinide (medicine for treating diabetes)
- suffer from porphyria (a disorder that causes skin sensitivity to light, pain attacks and muscle weakness)
- Trimethoprim should not be given to premature babies or babies during the first few weeks of
- life.

You should let your doctor know and ask his/her advice if you suffer from or have ever had any of the above.

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.

Your doctor may wish to do regular blood tests if you need long-term treatment or are prone to anaemia.

Take special care with Trimethoprim:
Serious skin reactions, such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with trimethoprim treatment. Stop using trimethoprim and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Trimethoprim Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those are not prescribed. Your medicine may interfere with other medicines that you are taking.

Take care with the following medicines:
- repaglinide, used to treat diabetes
- procainamide, to treat abnormal heart rhythm
- digoxin, to treat certain heart conditions
- 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)
- diuretics (water tablets such as furosemide, eplerenone, spironolactone, amiloride or triamterene)
- rifampicin (antibiotic), used to treat TB
- anticoagulants (to prevent clots from forming in the blood e.g. warfarin)
- phenytoin, to treat epilepsy
- pyrimethamine and dapsone, used 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
- spironolactone

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. Trimethoprim should not be used in pregnancy. DO NOT take Trimethoprim Tablets if you are pregnant.

This medicine should not be taken during first three months of pregnancy. Treatment with trimethoprim in the first three months of pregnancy may increase the risk of miscarriage.

Children born to mothers treated with trimethoprim during the first trimester of pregnancy may have an increased risk of birth defects, in particular neural tube defects (where the spine and spinal cord do not form properly), oral clefts (where the lip and palate do not form properly) and defects affecting the heart.

Trimethoprim is excreted in breast milk. If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine

Driving and using machines
There is no evidence to suggest that Trimethoprim Tablets affect the ability to drive or operate machinery.

Trimethoprim Tablets contain lactose
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Trimethoprim Tablets

- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Trimethoprim tablets are for oral administration only and should be swallowed with a drink of water. Do not crush or chew this tablets.

Dosage
Severe or sudden infections:
- Adults and children over 12 years: 200 mg twice daily.
- Children 6 years to 12 years: 100 mg twice daily.

Long-term treatment and prevention therapy:
- Adults and children over 12 years: 100 mg at night.
- Children 6-12 years: 50mg at night. Where a single daily dose is required, dosage at bedtime may maximise urinary concentrations.

The usual dose is around 2mg/kg body weight of the child per day.

Children: Trimethoprim tablets are **not recommended** for children **under 6 years** of age. Your doctor has carefully chosen the correct dosage for you, taking into account the severity of your condition, your age and any other particular reasons special to you. Instructions on how many tablets to take and when to take them will be printed on the dispensing label on the pack.

Never change the dose of your medicine without talking to your doctor first.

Elderly: doses may be reduced in elderly patients. Your doctor will prescribe a suitable dose depending on how well your kidneys are working.

If you take more of your medicine than you should
If you (your child or someone else) take too many tablets, tell a doctor or pharmacist or go to the nearest hospital casualty department straight away. Remember to take this leaflet and the tablet packaging with you.

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If you forget to take Trimethoprim tablets
If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking your medicine
Keep taking this medicine until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop taking this medicine, your condition may re-occur or get worse. If you experience symptoms on stopping treatment, contact your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Rare serious allergic reactions have occurred known as anaphylactic or anaphylactoid reactions.

Stop taking Trimethoprim and contact your doctor or go to a hospital straightaway if you experience any of the following:

- **Allergic reactions** such as swelling of the face, lips, tongue or throat, difficulty breathing, shock, fainting or collapse, skin eruptions/lesions, deep swelling of the skin (angioedema)
- Reddish patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens Johnson syndrome (SJS)/ Toxic Epidermal Necrolysis (TEN)).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)
- **Pancreatitis** (signs may include a sudden, severe upper abdominal pain)
- Jaundice (yellowing of the skin or whites of the eyes)
- Elevation of serum transaminases (an indication of liver damage)
- Elevation of bilirubin levels
- Chest 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)
- hyperkalaemia (particularly in the elderly and in HIV patients) which is 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, nausea, vomiting
- skin rashes, thrush
- hives, headaches

Very rare (may affect up to 1 in 10,000 people)
- constipation, severe watery/bloody diarrhoea
- 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)
- pins and needles, shakiness, tremors
- increased sensitivity of the skin to the sun
- low levels of sodium in the blood (may cause nausea, tiredness, muscle cramping)
- depression, anxiety, sleeping difficulties and nightmares
- shortness of breath, wheezing, nosebleeds
- lupus erythematosus (an auto-immune disorder - an allergic condition which causes joint pain, skin rashes and fever)
- purple discolorations of the skin
- allergic reaction (hypersensitivity, anaphylaxis), inflammation to small vessels (allergic vasculitis), drug allergy (anaphylactoid reaction drug fever)
- reduction in numbers of blood cells
- anaemia (decrease in red blood cells)
- sore tongue and mouth
- sore throat
- confusion, hallucinations
- joint and muscle ache
- anorexia (loss of appetite or a loss of interest in food)
- low blood sugar
- eye redness and pain
- convulsions (fits)
- cough
- agitation
- abnormal behaviour
- tiredness, dizziness
- involuntary movements
- ringing in the ears, vertigo (sense that your surroundings are spinning or moving)

Unknown (frequency cannot be estimated)
- sore throats or mouth ulcers (due to a decrease in white blood cells)
- Gastrointestinal disturbances (stomach discomfort)
- Pruritus (itching)
- Elevation of serum creatinine and blood urea nitrogen levels

If any side effects get 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, 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 Website: 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 Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use the tablets after the expiry date shown on the carton or label. The expiry date refers to the last day of that month.
- Blisters: Do not store above 25^{O}C.
  Store in the original package.
- Containers: Do not store above 25^{O}C. Store in the original container.
  Keep the container tightly closed.
- Do not throw away any medicines via waste water 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 tablets contain
- The active substance in Trimethoprim tablets is Trimethoprim
- The other ingredients in Trimethoprim tablets are Lactose monohydrate, povidone K-25, crospovidone, sodium starch glycolate, magnesium stearate.

What Trimethoprim tablets look like and contents of the pack.
- Trimethoprim tablets are white to off-white, circular, flat bevelled edged uncoated tablets with break line dividing 'TMP' and '100' or '200' on one side and plain on the other side.
- The containers are available in pack sizes of 50, 100, 250 and 500 tablets.
- The blister packs are available in sizes of 14, 28, 56, and 84 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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Trimethoprim 100mg Tablets; PL 17907/0092
Trimethoprim 200mg Tablets; PL 17907/0093

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