

Package leaflet: Information for the user

Trimethoprim 100 mg and 200 mg Tablets

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

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

- Trimethoprim Tablets contain the active substance trimethoprim. Trimethoprim belongs to a group of medicines called antibacterials.
- Trimethoprim is used for the prevention and treatment of infections, particularly in the urinary and respiratory tracts.

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

Do not take Trimethoprim Tablets if you:

- are allergic to trimethoprim or any of the other ingredients of this medicine (listed in section 6)
- are pregnant (first 3 months) or might be pregnant or breast-feeding
- suffer from any blood disorders such as anaemia
- suffer from severe liver problems

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. Alternative dosage forms are available.

Tell your doctor before taking Trimethoprim Tablets if you:

- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking trimethoprim.

Warnings and precautions

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

- have kidney problems/kidney disease or are having dialysis treatment
- have folate-deficiency anaemia (a decrease in red blood cells due to a poor diet, which can cause tiredness, headache, a sore mouth and tongue and pale skin)

- 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 (a medicine for treating diabetes)
- suffer from porphyria (a disorder that causes skin sensitivity to light, pain attacks and muscle weakness)

Trimethoprim Tablets 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 Tablets:

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.

Children

This dosage form is not suitable for use in children younger than 6 years.

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 not prescribed.

The effect of Trimethoprim may be increased or decreased by other medicines and vice versa. These medicines include:

- Azathioprine (used following organ transplant and for arthritis)
- Ciclosporin (used to prevent organ rejection after transplant surgery)
- Digoxin or procainamide (used to treat heart problems)
- Mercaptopurine or methotrexate (used as bone marrow depressants)
- Phenytoin (used to treat epilepsy)
- Pyrimethamine and dapsone (used to treat malaria)
- Rifampicin (used to treat infections)
- Warfarin (used to prevent blood clots)
- Spironolactone, eplerenone, furosemide, amiloride or triamterene (water pill)
- 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 (used to treat diabetes)

Pregnancy, breast-feeding and fertility

Do not take Trimethoprim Tablets if you are pregnant. If you are planning to become pregnant or breast-feeding, ask your doctor for advice before taking this medicine.

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.

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.

Driving and using machines

Taking this medicine should not affect your ability to drive or operate machinery, however, if you think you are affected you should not drive or operate machinery until you feel better.

Important information about some of the ingredients of Trimethoprim Tablets

This medicine contains sodium

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

This medicine contains Lactose

Patients who are intolerant to **lactose** should note that Trimethoprim tablets contain a small amount of **lactose**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Trimethoprim Tablets

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

The tablets should be swallowed with a drink of water. The recommended dose is:

Severe or sudden infections:

Adults and children over 12 years of age: 200 mg twice a day.

Children aged 6 to 12: 100 mg twice a day.

Children under 6 years of age: Not recommended; a more suitable dosage form should be used in this age group.

Trimethoprim suspension is available for use in children.

Elderly: The adult dose may need to be reduced depending on how well your kidneys function. Your doctor will advise you.

The treatment should continue for at least one week but no longer than two weeks.

For long term treatment and for the prevention of infections:

Adults and children over 12 years of age: 100 mg at night.

Children under 12 years of age: Not recommended; a more suitable dosage form should be used in this age group. Trimethoprim suspension is available for use in children.

Elderly: The adult dose may need to be reduced depending on how well your kidneys function. Your doctor will advise you.

Renal impairment:

It may be necessary to reduce the dosage if you are suffering from kidney problems. Your doctor will advise you.

You should continue to take these tablets for as long as your doctor tells you to. Take the full course. Even if you start to feel better the original infection may still be present and may recur if treatment is stopped.

You may need to have blood tests if you take Trimethoprim for a long time or if your doctor thinks you are at special risk.

If you take more Trimethoprim Tablets than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has accidentally swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Trimethoprim Tablets

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten tablet. Take the remaining doses at the correct time.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking Trimethoprim Tablets

You must continue to take the complete course of tablets that your doctor has prescribed for you. If you stop taking the tablets before the course is finished your original symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist.

4. Possible side effects

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

Serious side effects

If the following happens, stop taking Trimethoprim and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty in breathing and swelling of the lips, face and neck
- Chest pain
- Shock, fainting or collapse
- Pancreatitis (signs may include a sudden, severe upper abdominal pain)
- Skin eruptions/lesions
- Jaundice (yellowing of the skin or whites of the eyes)
- Elevation of serum transaminases (an indication of liver damage)
- Elevation of bilirubin levels

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.

- severe skin reactions such as exfoliative dermatitis (itchy, scaly, flaking, swollen skin), erythema multiforme (circular, irregular red patches),
- 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)

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

Other side effects

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

- High levels of potassium in the blood (hyperkalaemia), particularly in the elderly and in HIV patients (may result in abnormal heart rhythm)

Common (may affect up to 1 in 10 people)

- Feeling sick (nausea), being sick (vomiting) and diarrhoea
- Headache
- Skin rashes

- Thrush
- Hives

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

- Constipation, severe watery/bloody diarrhoea
- Sore tongue and mouth
- 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
- Joint and muscle ache
- Shortness of breath, wheezing, nosebleeds
- Lupus erythematosus (an auto-immune disorder)
- Purple discolouration of the skin
- Hypersensitivity, anaphylaxis, anaphylactoid reaction, drug fever, allergic vasculitis
- Reduction in the number of blood cells
- Anaemia
- Sore throat

Not known (frequency cannot be estimated from the available data)

- Pruritus (itching)
- Elevation of serum creatinine and blood urea nitrogen levels
- Sore tongue and mouth, gastro-intestinal disturbances.

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 Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. 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 to protect the environment.

6. Contents of the pack and other information

What Trimethoprim Tablets contains:

- The active ingredient is Trimethoprim 100 or 200 mg. Each tablet contains 100 or 200 mg of the active substance, trimethoprim.
- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycolate (Type A), povidone, colloidal anhydrous silica, magnesium stearate and stearic acid.

What Trimethoprim Tablets looks like and contents of the pack:

- The name of your medicine is Trimethoprim 100 or 200 mg Tablets
- Trimethoprim 100 mg Tablets are white, normal biconvex tablets, engraved “Berk 2H7” or “2H7” with a breakline on reverse. The breakline is only there to help you break the tablet if you have difficulty swallowing it whole.
- Trimethoprim 200 mg Tablets are white, normal biconvex tablets, engraved “Berk 3H7” or “3H7” with a breakline on the reverse. The breakline is only there to help you break the tablet if you have difficulty swallowing it whole.
- The 100 mg product is available in pack sizes of 7, 10, 14, 20, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168, 500 and 5000 tablets
- The 200 mg product is available in pack sizes of 7, 10, 14, 21, 24, 28, 30, 50, 56, 60, 70, 84, 90, 100, 110, 112, 120, 150, 160, 168 and 500 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

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