

Trimethoprim 100mg and 200mg tablets

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

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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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 Before you take

Do not take Trimethoprim tablets and **tell your doctor** if you:

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

Check with your doctor or pharmacist before taking Trimethoprim tablets if you have:

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

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- antibiotics such as rifampicin
- anticoagulants to prevent your blood clotting such as warfarin
- 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
- spironolactone (to treat fluid build up)
- repaglinide (to treat diabetes)
- diuretics (e.g. water tablets such as frusemide or eplerenone)
- procainamide, to treat abnormal heart rhythm.

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 you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

Blood tests

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

3 How to take

Always take Trimethoprim tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets **with a glass of water** at the same times each day.

Doses:

- **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.

If you take more than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately.

If you forget to take the 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 the tablets

Do not stop taking Trimethoprim tablets because you feel better. Take the tablets for as long as your doctor has told you or your problem may come back.

4 Possible side effects

Like all medicines, Trimethoprim 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 and 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

Keep out of the reach and sight of children. Store below 25°C in a dry place.

Do not use Trimethoprim tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Trimethoprim tablets contain

- The active substance (the ingredient that makes the tablets work) is trimethoprim. Each tablet contains either 100mg or 200mg of the active substance.
- The other ingredients are colloidal silicon dioxide, lactose, macrogol, magnesium stearate, povidone, sodium starch glycolate, stearic acid, microcrystalline cellulose (E460).

What Trimethoprim tablets look like and contents of the pack

Trimethoprim tablets are white, circular, uncoated tablets.

Pack sizes are 6, 14 and 28 tablets

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK

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Actavis, Barnstaple, EX32 8NS, UK