

1.3.1 PACKAGE LEAFLET

PATIENT INFORMATION LEAFLET

TRIMETHOPRIM 100mg AND 200mg TABLETS

Read all of this leaflet carefully 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.**
- **If any side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

IN THIS LEAFLET

1. What Trimethoprim Tablets are and what they are used for
2. Before you take Trimethoprim Tablets
3. How to take Trimethoprim Tablets
4. Possible side effects
5. How to store Trimethoprim Tablets
6. Further information

1. WHAT TRIMETHOPRIM TABLETS ARE AND WHAT THEY ARE USED FOR

Trimethoprim Tablets belong to a group of medicines known as antibacterials. They are used to kill bacteria that cause infections in your body, primarily urinary and respiratory tract infections.

2. BEFORE YOU TAKE TRIMETHOPRIM TABLETS

DO NOT take Trimethoprim Tablets if you:

- are allergic (hypersensitive) to trimethoprim or to any of the other ingredients (see section 6, Further information)
- are pregnant
- suffer from severe kidney or liver problems
- suffer from any blood disorders such as anaemia

Trimethoprim should not be administered to 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.

Take special care with Trimethoprim Tablets if you:

- suffer from kidney problems
- have a deficiency (are low) in folic acid
- 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)

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

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

Taking other medicines

Your medicine may interfere with other medicines that you are taking. Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicines, even those not prescribed.

Take care with the following medicines:

- repaglinide, used to treat diabetes
- procainamide, to treat abnormal heart rhythm
- digoxin, to treat certain heart conditions
- diuretics (e.g. water tablets such as frusemide or eplerenone)
- rifampicin, 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)

Pregnancy and breast-feeding

DO NOT take Trimethoprim Tablets if you are pregnant or breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Trimethoprim Tablets

These tablets contain lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE TRIMETHOPRIM TABLETS

Trimethoprim Tablets should be taken orally according to your doctor's instructions.

They can be swallowed with a glass of water but not chewed.

Dosage

Adults and children over 12 years

Severe or sudden infections: usually your doctor will prescribe 200mg taken twice daily

Long term treatment and prevention therapy: 100mg at night

Elderly

Dosage is dependent on kidney function.

Elderly patients with kidney problems will usually be prescribed a reduced dose.

Children aged 6 – 12 years

Severe or sudden infections: 100mg twice daily

Long term treatment and prevention therapy: 50mg at night

This tablet form of Trimethoprim is not recommended for use in children under 6 years.

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.

If you take more of your medicine than you should

If you (or your child) 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.

If you forget to take your medicine

If you do forget to take a dose of your medicine at the correct time, take it as soon as you remember, then carry on as before. DO NOT take a double 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.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, Trimethoprim Tablets can have side-effects, although not everybody gets them.

Rare serious allergic reactions have occurred known as anaphylactic or anaphylactoid reactions.

STOP taking Trimethoprim Tablets 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 tongue and throat
- chest pain
- fainting
- blistering/peeling of the skin
- pancreatitis (signs may include a sudden, severe upper abdominal pain)
- skin eruptions/lesions
- deep swelling of the skin (angioedema)

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

Common (occurs in more than 1 in 10 and less than 1 in 100 people)

- feeling and being sick, diarrhoea
- headache
- skin rashes
- high levels of potassium in the blood (may result in abnormal heart rhythm)
- 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 (occurs in less than 1 in 10,000 people)

- constipation, severe watery/bloody diarrhoea
- sore tongue and mouth
- cough
- agitation
- abnormal behaviour
- jaundice (yellowing of the skin or whites of the eyes)
- kidney problems (signs may include painful urination or blood in the urine)
- dizziness, tiredness
- convulsions
- involuntary movements
- pins and needles, shakiness
- 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
- confusion, hallucinations
- elevation of serum transaminases (an indication of liver damage)
- elevation of bilirubin levels
- joint and muscle ache
- wheezing, nosebleeds
- meningitis (signs may include stiff neck, fever and vomiting)
- lupus erythematosus (an auto-immune disorder)

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

Also you can help to make sure that 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 0800 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

5. HOW TO STORE TRIMETHOPRIM TABLETS

Do not use Trimethoprim Tablets after the 'expiry date' printed on the pack.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Store your tablets below 25°C (room temperature) in a dry place and protect from light.

Keep it in the pack in which it was given to you. Do not transfer your tablets to another container.

Return any leftover tablets to your pharmacist, unless your doctor tells you to keep them.

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

Trimethoprim Tablets are available in two strengths, 100mg and 200mg.

The active ingredient is trimethoprim, which is an antibiotic.

Other ingredients are lactose monohydrate, povidone K30, crospovidone, sodium starch glycolate Type A and magnesium stearate.

What Trimethoprim Tablets look like and contents of the pack

Trimethoprim 100mg tablets are available in pack sizes of 28, 100 and 500. The tablets are flat, white tablets and contain the marking TR100.

Trimethoprim 200mg Tablets are available in pack sizes of 6, 14, 100 and 500. The tablets are flat, white tablets and contain the marking TR200.

Marketing Authorisation Holder

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

Distributor

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

Manufacturers responsible for batch release

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

PL 06453/0043-44

This leaflet was revised in June 2013.