CP.TRM.JNT.T.FL.V11P1

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

TRIMETHOPRIM 100mg AND 200mg 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. This includes any 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

Trimethoprim Tablets belong to a group of medicines known as antibacterials. They are used to kill a wide range of bacteria that cause infections in your body, primarily urinary and respiratory tract infections. This medicine can also be used for 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 to any of the other ingredients (see section 6, Contents of the pack and other information)
- are pregnant
- suffer from severe liver problems
- suffer from any blood disorders such as anaemia

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:
- 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
- suffer from porphyria (a disorder that causes skin sensitivity to light, pain attacks and muscle weakness)
- If you have fructose intolerance or an intolerance to some sugars

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.

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

Other medicines and Trimethoprim
Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicines, even those 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.
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.

Important information about some of the ingredients of Trimethoprim Tablets
These tablets contain a sugar called lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg), 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. They can be swallowed with a glass of water, but not chewed, at the same time each day.

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

Children under 6
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 (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.

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 take the next dose at the right time. 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.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Trimethoprim Tablets can cause 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 face, lips, tongue and throat
- chest pain
- shock, fainting or collapse
- blistering/peeling of the skin
- pancreatitis (signs may include a sudden, severe upper abdominal pain)
- skin eruptions/lesions
- deep swelling of the skin (angioedema)
- jaundice (yellowing of the skin or whites of the eyes)
- elevation of serum transaminases (an indication of liver damage)
- elevation of bilirubin levels

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)
- headache
- skin rashes
- hives
- thrush
- nausea, diarrhoea, vomiting

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
- joint and muscle ache
- shortness of breath, wheezing, nosebleeds
- lupus erythematosus (an auto-immune disorder)
- purple discolorations of the skin
- hypersensitivity, anaphylaxis, anaphylactoid reaction drug fever, allergic vasculitis
- reduction in numbers of blood cells
- sore tongue and mouth
- anaemia
- sore throat

Unknown (frequency cannot be estimated)
- pruritus (itching)
- elevation of serum creatinine and blood urea nitrogen levels
- gastro-intestinal disturbances

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 or pharmacist. 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 Trimethoprim Tablets after the 'expiry date' printed on the pack. The expiry date refers to the last day of that month.
Store your tablets below 25ºC (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. CONTENTS OF THE PACK AND OTHER 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
Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturers responsible for batch release
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

PL 51463/0118-0119

This leaflet was revised in October 2023.

CP.TRM.JNT.T.FL.V11P1

Customer: FL **Originated by:** ABC (AWG)

Product: Trimethoprim JNT Tablets

Dimensions: 210mm x 297mm

Item Code: CP.TRM.JNT.T.FL.V10P1

Proof No and Date: 1 02/10/2023

Revision: Removal of Ashford as BR site
ARTWORK FOR SUBMISSION
Supersedes: CP.TRM.JNT.T.FL.1V0P1

Colours
Pantone 280 C