# PACKAGE LEAFLET: INFORMATION FOR THE USER

### Trimethoprim 100mg and 200mg Tablets

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#### 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, pharmacist or nurse.
- 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, pharmacist or nurse. 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
- Possible side effects
- 5. How to store Trimethoprim Tablets
- 6. Contents of the pack and other information

#### WHAT TRIMETHOPRIM TABLETS ARE AND WHAT THEY ARE USED FOR

Trimethoprim Tablets contain the active substance trimethoprim. Trimethoprim is a type of antibacterial medicine which works by killing bacteria.

Trimethoprim is most commonly used for prevention and treatment of infections of the urinary tract and respiratory tract (for example in the chest).

WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRIMETHOPRIM TABLETS

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. Your medicine may interfere with other medicines that you are taking. In particular:

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- 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 (e.g. 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

This medicine should not be taken during pregnancy. 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 is excreted in breast milk. If you are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine.

### 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 vou feel better.

# Your doctor has carefully chosen the correct dosage for you, taking into account the severity of your condition.

#### If you take more Trimethoprim Tablets than you should

If you accidently take one extra dose, this should not be a problem. If you (or someone else) swallows a lot of tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or doctor immediately.

#### If you forget to take Trimethoprim Tablets

If you 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 to make up for a forgotten dose.

#### 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 or nurse.

#### 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 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

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• Eye redness and pain Low blood sugar 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.

#### Depression, anxiety, sleeping difficulties and nightmares Confusion, hallucinations

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Joint and muscle ache

Anorexia

Shortness of breath, wheezing, nosebleeds

Increased sensitivity of the skin to the sun

nausea, tiredness, muscle cramping)

Low levels of sodium in the blood (may cause

- 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 label and the carton. The expiry date refers to the last day of that month.

Trimethoprim 100mg Tablets: Protect from light. Store in a cool dry place. Trimethoprim 200mg Tablets: Store below 25°C. Keep them in the packaging they came in. Do not transfer them to another container.

• are allergic to trimethoprim or any of the other ingredients of this medicine (listed in section 6)

Do not take Trimethoprim Tablets if you:

- 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. Alternative dosage forms are available.

#### Warnings and precautions

Talk to your doctor, pharmacist or nurse 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
- 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).

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

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.

#### Children

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

#### Trimethoprim Tablets contain lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

#### 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. Swallow the tablets with a little water.

The recommended dose of Trimethoprim for different conditions is shown below:

#### 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 years

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

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- 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

Severe skin reactions such as erythema multiforme (circular, irregular red patches), Stevens-Johnson syndrome (severe skin rash with flushing, fever, blisters and ulcers), toxic epidermal necrolysis (severe rash involving reddening, peeling and swelling of the skin that resembles severe burns), may also be signs of an allergic reaction.

#### 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 (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
- 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

#### Do not use this medicine if you notice any visible signs of deterioration, such as chipped or broken tablets. Take them to your pharmacist for advice.

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 protect the environment.

## CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Trimethoprim Tablets contain

Trimethoprim Tablets 100mg contain 100mg of the active ingredient, trimethoprim. Trimethoprim Tablets 200mg contain 200mg of the active ingredient, trimethoprim.

The other ingredients are lactose, povidone, microcrystalline cellulose, sodium starch glycollate and magnesium stearate.

#### What Trimethoprim Tablets look like and contents of the pack

Trimethoprim Tablets 100mg are white, round, flat faced bevelled edge tablet with an approximate diameter of 7.5mm, embossed with 'T2' on one side and plain on the other side.

Trimethoprim Tablets 200mg are white, round, biconvex tablets with an approximate diameter of 9.0mm, embossed with 'T & 3' separated by a score line on one side and plain on the other side. The score line is not intended for breaking the tablet.

Trimethoprim Tablets are supplied in the following pack sizes: 100mg: 28 tablets 200mg: 14 tablets

#### Marketing Authorisation Holder

Ennogen IP Ltd. Unit G4, Riverside Industrial Estate, Riverside Way, Dartford, DA1 5BS, UK.

#### Manufacturer

Ennogen Pharma Limited Unit G4, Riverside Industrial Estate, Riverside Way, Dartford, DA1 5BS, UK.

#### This leaflet was last revised in February 2024.

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