

## PATIENT INFORMATION LEAFLET

**TRIMOPTIN  
TABLETS 100mg**

**TRIMOPTIN  
TABLETS 200mg**

(Trimethoprim)

**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 of these 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 Trimoptin Tablets are and what they are used for
2. What you need to know before you take Trimoptin Tablets
3. How to take Trimoptin Tablets
4. Possible side effects
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### **1. WHAT TRIMOPTIN TABLETS ARE AND WHAT THEY ARE USED FOR**

Trimoptin Tablets belong to a group of medicines known as antibacterials and they contain Trimethoprim as the antibiotic. They are used to treat infections in your body, primarily urinary and respiratory tract infections and for the prevention of recurrent urinary tract infections.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRIMOPTIN TABLETS**

#### **Do not take Trimoptin Tablets if you:**

- are allergic to trimethoprim, or to any of the other ingredients mentioned in Section 6 (consult your doctor if you think you might be)
- suffer from severe kidney or liver impairment
- suffer with fragile X chromosome (an inherited physical and intellectual impairment)
- suffer with porphyria (a disorder that may cause skin sensitivity to the sun, pain attacks and muscle weakness)
- suffer from anaemia or other blood disorders
- are pregnant or planning to become pregnant
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking trimethoprim.

Trimethoprim is not suitable for babies less than 6 weeks old.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Trimoptin Tablets:

- if you suffer from kidney or liver impairment or are having dialysis treatment
- if you are receiving long-term treatment or are prone to anaemia, as your doctor may wish to do regular blood tests
- if you have a deficiency (are low) in folic acid – if you are elderly, you may be more likely to be low in folic acid

- if you are taking other types of medicine, such as potassium conserving water tablets as your doctor may wish to check your blood levels of potassium
- if you are taking the medicine repaglinide (to treat diabetes)
- if you have been told by your doctor that you have an intolerance to some sugars, as this medicine contains lactose
- if you are breast-feeding
- if you are elderly

Trimoptin Tablets can interfere with some diagnostic kidney function and blood tests.

Concomitant administration of Trimoptin with certain medicines such as potassium-sparing diuretics, potassium supplements, potassium-containing salt substitutes, renin angiotensin system inhibitors (e.g.: ACE inhibitors or renin angiotensin receptor blockers), or those patients taking other drugs associated with increases in serum potassium (e.g. heparin) and food rich in potassium may lead to severe hyperkalaemia (increased potassium blood level). Also patients with poorly controlled diabetes mellitus can also lead to increase in potassium levels. The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.

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**

Trimethoprim is NOT recommended for use in infants under 6 weeks of age.

**Trimoptin Tablets are not recommended for use in children under 12 years of age – other forms of medicine may be more suitable for children: please ask your doctor or pharmacist.**

### **Other medicines and Trimoptin Tablets**

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:

- Immunosuppressant drugs - used in cancer treatment (e.g. methotrexate) or to treat organ rejection after transplant or depress bone marrow (e.g. azathioprine or ciclosporin)
- Mercaptopurine (used to treat leukaemia)
- Warfarin and other anticoagulant drugs (used to prevent clots from forming in the blood)
- Diuretics (water tablets), e.g. furosemide, eplerenone, bendroflumethiazide, spironolactone, amiloride or triamterene
- Medicines likely to increase the amount of potassium in your blood (e.g. potassium supplements), used to treat high blood pressure such as ACE inhibitors e.g. ramipril, lisinopril, angiotensin II antagonists and heparin
- Medicines used to treat irregular heartbeat and heart failure, e.g. digoxin, procainamide, dofetilide and amiodarone
- Anticonvulsants (medicines used to treat epilepsy) such as phenytoin
- Repaglinide (to treat diabetes)
- Pyrimethamine, used to treat malaria
- Rifampicin (used to treat TB)
- Oral contraceptives (the pill and oestrogen-containing contraceptives) – other forms of contraception, such as condoms, should be used during treatment and for the following

7 days. Ask your doctor or pharmacist about alternative contraception.

- Lamivudine, a medicine used to treat HIV
- Oral typhoid vaccine
- Spironolactone
- medicine likely to depress bone marrow (e.g. mercaptopurine, azathioprine)
- dapsone, a medicine used to treat skin infections.

Blood monitoring may be carried out if taking these drugs with Trimoptin Tablets. If you are unsure whether you are taking any of the above medicines, show the containers of the medicines you are taking to your doctor or pharmacist.

### **Pregnancy and breast-feeding**

DO NOT take Trimoptin Tablets if you are pregnant. Trimoptin Tablets can pass into breast milk; if you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

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**

This medicine may cause side-effects such as dizziness, difficulty with movement control, fainting or eye pain (for more information see 'Possible Side Effects' below). Do not drive or operate machinery until you know how this medicine affects you.

### Trimoptin contains sodium

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

### **Trimoptin Tablets contain lactose**

These tablets contain lactose monohydrate. 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 TRIMOPTIN TABLETS**

Trimoptin 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:**

*Treatment of Respiratory and Urinary Tract Infections:* usually your doctor will prescribe 200mg, taken twice daily for 7 to 10 days.

*Prevention of Recurrent Urinary Tract Infections:* 100mg at night is the usual dose.

### **Elderly**

Elderly patients with kidney problems will usually be prescribed a reduced dose. Elderly patients should be monitored carefully because of the increased risk of side effects, which can be fatal.

### **Children under 12 years**

Trimethoprim is NOT recommended for use in infants under 6 weeks of age.

**Trimoptin Tablets are not recommended for use in children under 12 years of age – other forms of medicine may be more suitable for children: please ask your doctor or pharmacist.**

### **Kidney Problems**

Patients suffering from kidney problems will usually be prescribed a reduced dose.

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 of 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 Trimoptin Tablets than you should**

If you take too much medicine, contact your doctor or pharmacist or nearest hospital casualty department who will recommend what action you should take. Remember to take the Trimoptin Tablets packaging with you.

### **If you forget to take Trimoptin Tablets**

If you 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 Trimoptin Tablets**

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, Trimoptin Tablets can have side effects although not everybody gets them. Rarely, serious allergic reactions have occurred known as anaphylactic or anaphylactoid reactions.

**Should you notice any of the following symptoms, STOP taking Trimoptin Tablets and contact your doctor immediately or go to your nearest hospital casualty department:**

- Allergic reaction – signs may include swelling of the face, lips, tongue, or throat, difficulty breathing, shortness of breath, wheezing, shock or collapse, skin eruptions or lesions, severe itching of the skin, deep swelling of the skin (angioedema)
- Severe diarrhoea, possibly with bleeding
- Jaundice (skin and whites of your eyes may turn yellow), which may be fatal
- 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)

**Tell your doctor as soon as possible if you notice any of the following side effects:**

**Very common side effects** (occurs in more than 1 in 10 people)

- Hyperkalaemia (high levels of potassium in the blood): symptoms include pins and needles in the fingers and toes, muscle weakness, paralysis

**Common side effects** (occurs in up to 1 in 10 people)

- Thrush
- Headache
- Skin rashes including itching (pruritis), hives and ‘nettle rash’ (urticaria)

**Very rare side effects** (occurs in less than 1 in 10,000 people)

- Blood disorders. If you notice increased sore throats or infections; nosebleeds or unusual bruising; or anaemia (causes skin to be pale, weakness and breathlessness), you should consult your doctor.
- Sore mouth or tongue
- Hypoglycaemia (low blood sugar)
- Hyponatraemia (low blood sodium) – can cause tiredness, confusion, muscle twitching and coma
- Constipation
- Depression, confusion, agitation, anxiety, abnormal behaviour
- Hallucinations, nightmares, difficulty in sleeping
- Kidney problems (you may notice difficulty in passing urine or presence of blood in the urine)
- Tremors, difficulty in controlling movements
- Vertigo, tinnitus (ringing in the ears)
- Dizziness, fainting, weakness
- Very severe abdominal pain (which may indicate inflammation of the pancreas)
- Sensitivity of skin to light (photosensitivity)
- Muscle or joint pain
- Convulsions
- Loss of appetite
- Anorexia
- Cough, shortness of breath, wheeze
- Lupus erythematosus (an auto-immune disorder)

**Not known: cannot be estimated from the available data.**

- Aseptic meningitis – symptoms may include, headache, fever, stiff neck, tiredness, feeling ill and sensitivity to light (reversible on discontinuation of treatment)
- Feeling sick (nausea), vomiting, diarrhoea, gastrointestinal upset
- Disturbances in Liver enzymes
- Painful, red eyes (uveitis)

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE TRIMOPTIN TABLETS**

Do not use Trimoptin Tablets after the ‘Expiry’ date printed on the box. The expiry date refers to the last day of the month.

**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**

Store your tablets below 25°C (room temperature) and protect from light. Store in the original package. If your doctor tells you to stop taking your medicine you should return any leftover tablets to the pharmacist, unless your doctor tells you to keep them.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Trimoptin Tablets contain**

The active ingredient is trimethoprim, 100mg or 200mg, which is an antibiotic. Other ingredients are lactose monohydrate, povidone, crospovidone, sodium starch glycolate and magnesium stearate.

### **What Trimoptin Tablets look like and contents of the pack**

Trimoptin Tablets are available in two strengths, 100mg and 200mg. Trimoptin Tablets 100mg and 200mg are available in securitainer packs of 100 and 500.

Trimoptin Tablets 100mg and 200mg are available in blister packs of 28.

The tablets are flat white tablets and contain the marking TR 100 on the 100mg strength tablet and TR 200 on the 200mg strength.

### **Marketing Authorisation Holder:**

Athlone Pharmaceuticals Limited, Connaught House, 1 Burlington Road, Dublin 4, Ireland.

### **Manufacturer Responsible for Batch Release**

Athlone Pharmaceuticals Limited, Maple House, South County Business Park, Dublin 18, Ireland.

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