1. What Trimoptin Tablets are and what are they 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 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

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 have been told by your doctor that you have an intolerance to some sugars, as 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.
- if you are taking the medicine repaglinide (to treat diabetes)
- if you are taking other types of medicine, such as potassium conserving water tablets 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 receiving long-term treatment or are prone to anaemia, as your doctor may wish to do regular blood tests
- if you are taking other medicines, even those not prescribed. 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.

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. Talk to your doctor or pharmacist before taking the following medicines:
- Immunosuppressant drugs - used in cancer treatment (e.g. methotrexate) or to treat organ rejection after transplant (e.g. azathioprine or cyclosporin)
- 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
- ACE inhibitors (used to treat high blood pressure, e.g. ramipril)
- 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 and dapson (used to treat TB)
- Oral contraceptives (the pill) – other forms of contraception, such as condoms, should be used during treatment and for the following 7 days
- Oral typhoid vaccine

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.

3) How to store Trimoptin Tablets

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

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.

Talk to your doctor or pharmacist before taking the following medicines:
- Immunosuppressant drugs - used in cancer treatment (e.g. methotrexate) or to treat organ rejection after transplant (e.g. azathioprine or cyclosporin)
- 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
- ACE inhibitors (used to treat high blood pressure, e.g. ramipril)
- 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 and dapson (used to treat TB)
- Oral contraceptives (the pill) – other forms of contraception, such as condoms, should be used during treatment and for the following 7 days
- Oral typhoid vaccine

Pregnancy and breast-feeding

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

Driving and using machines

This medicine may cause side-effects such as dizziness, difficulty with movement control, fainting or eye sensitivity to light (reversible on discontinuation of treatment)

Aseptic meningitis – symptoms may include, headache, fever, stiff neck, tiredness, feeling ill and feeling unwell

Lupus erythematosus (an auto-immune disorder)

Cough, shortness of breath, wheeze

Loss of appetite

Convulsions

Muscle or joint pain

Sensitivity of skin to light (photosensitivity)

Very severe abdominal pain (which may indicate inflammation of the pancreas)

Dizziness, fainting, weakness

Painful, red eyes (uveitis)

Kidney problems (you may notice difficulty in passing urine or presence of blood in the urine)

Hallucinations, nightmares, difficulty in sleeping

Constipation

Hyponatraemia (low blood sodium) – can cause tiredness, confusion, muscle twitching and coma

Blood disorders. If you notice increased sore throats or infections; nosebleeds or unusual bruising; fever; or anaemia (causes skin to be pale, weakness and breathlessness), you should consult your doctor.

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.
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 container 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. Serious allergic skin reactions known as Stevens-Johnson syndrome and toxic epidermal necrolysis also occur rarely.

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, deep swelling of the skin (angioedema)
- Blistering/peeling of the skin
- Severe diarrhoea, possibly with bleeding
- Jaundice (skin and whites of your eyes may turn yellow), which may be fatal

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

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

- Hyperkalaemia (high levels of potassium in the blood): symptoms include pins and needles in the fingers and toes, muscle weakness, paralysis
- Thrush
- Headache
- Feeling sick (nausea), vomiting, diarrhoea
- 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
- Hyperglycaemia (high blood sugar)
- Hypofoamia (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)
- Painful, red eyes (uvitis)
- 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
- Cough, shortness of breath, wheeze
- Lupus erythematosus (an auto-immune disorder)
- Aseptic meningitis – symptoms may include, headache, fever, stiff neck, tiredness, feeling ill and sensitivity to light (reversible on discontinuation of treatment)

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Trimoptin Tablets
Do not use Trimoptin Tablets after the ‘Expiry’ date printed on the box.
Store your tablets below 25°C (room temperature) and protect from light.
Keep it in the pack in which it was given to you.

If you take too much medicine, contact your doctor or nearest hospital casualty department:

- Tell your doctor as soon as possible if you notice any of the following side effects:
- Store your tablets below 25°C (room temperature) and protect from light.
- Keep it in the pack in which it was given to you.
- Do not transfer your medicine to another container.

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 are available in packs of 100 and 500.
Trimoptin Tablets 200mg are available in packs of 100 and 500.
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 and Manufacturer
Manufacturer: Dragenopharm, Göllstraße 1, D-84529 Tittmoning, Germany.
Distributor: Athlone Laboratories Limited, Ballymurry, Co. Roscommon, Ireland.

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