PACKAGE LEAFLET

Package leaflet: Information for the user

Monotrim 100 mg Tablets
Monotrim 200 mg Tablets
(referred to as "Monotrim Tablets" throughout the text)

Trimethoprim

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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Monotrim Tablets are and what they are used for
2. What you need to know before you take Monotrim Tablets
3. How to take Monotrim Tablets
4. Possible side effects
5. How to store Monotrim Tablets
6. Contents of the pack and other information

1. What Monotrim Tablets are and what they are used for

Monotrim Tablets contain trimethoprim which is an antibiotic.
It is used to treat certain infections caused by bacteria sensitive to trimethoprim such as:
- urinary tract infections
- chest infections.

Trimethoprim may also be given to patients who often suffer from urinary tract infections, to stop the infections from returning.

2. What you need to know before you take Monotrim Tablets

Do NOT take Monotrim Tablets:
- if you are allergic to trimethoprim or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or might be pregnant or planning to become pregnant
- if you have a blood disorder
- if you have severely reduced liver function

Do not give Monotrim Tablets to very young babies (premature babies or babies less than 6 weeks old).
If any of the above apply to you, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Monotrim Tablets:

- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking trimethoprim (see below)
- if you have a folic acid deficiency
- if you have kidney problems or are having dialysis treatment
- if you have high concentration of potassium ions in the blood
- if you are elderly
- if you are breast-feeding
- if you have been told that you have or are at risk of having a rare blood disease called porphyria which can affect the skin or nervous system.

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 Monotrim Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Monotrim 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.

Other medicines and Monotrim Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may be affected by Monotrim Tablets or they may affect how well Monotrim Tablets will work.

Tell your doctor or pharmacist if you are taking:

- anticonvulsants for epilepsy or related conditions, particularly phenytoin
- diuretics (water tablets) e.g. bendroflumethiazide, eplerenone, spironolactone, amiloride or triamterene
- medicines likely to increase the amount of potassium in your blood (e.g. potassium supplements, angiotensin-converting enzyme (ACE) inhibitors such as lisinopril, angiotensin II antagonists, heparin)
- digoxin, a medicine used to treat heart conditions
- medicines to stop the blood clotting or thin the blood (e.g. warfarin)
- ciclosporin, a medicine used to suppress the immune system
- folate antagonists, medicines used to treat rheumatoid arthritis or cancer (e.g. methotrexate or 5-fluorouracil)
- medicine likely to depress bone marrow (e.g. mercaptopurine, azathioprine)

- procainamide, a medicine used to treat certain heart conditions
- repaglinide, a medicine used to treat diabetes
- dapsone, a medicine used to treat skin infections
- pyrimethamine, a medicine used to prevent malaria
- lamivudine, a medicine used to treat HIV
- rifampicine, a medicine to treat tuberculosis and other severe infections
- dofetilide, a medicine to treat heart arrythmias
- oral typhoid vaccine, a medicine used to protect against typhoid fever.

Blood monitoring may be carried out if taking these drugs with Monotrim 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.

Trimethoprim may cause an error in the investigations of your creatinine and methotrexate levels in your blood.

Pregnancy and breast-feeding

Pregnancy
DO NOT take Monotrim Tablets if you are pregnant as it may affect your unborn baby.

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.

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.

Breast-feeding
Monotrim Tablets can pass into breast milk; therefore care should be taken if breast-feeding.

Driving and using machines
Monotrim Tablets is unlikely to affect your ability to use machinery or to drive.

Monotrim Tablets contains lactose
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 Monotrim 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.
Your doctor will decide on the appropriate dose to suit your condition. Ask your doctor or pharmacist if you are not sure.

If you suffer from a kidney complaint, your doctor will decide the correct dosage for you.

- Swallow the tablets with a drink of water.

Use in children

Monotrim Tablets are not recommended for children under 12 years, talk to your doctor about other suitable preparations.

The recommended dose is:

Doses to treat urinary tract or chest infections

Adults and adolescents over 12 years: the usual dose is 200 mg twice a day for 7-10 days. Your doctor may tell you to take double the dose on the first day (i.e. 400 mg).

Doses to prevent urinary infections

Adults and adolescents over 12 years: the usual dose is 100 mg at night. Your doctor may tell you to take 100 mg in the morning as well.

Elderly

Your doctor may prescribe a lower dose. You will be advised by your doctor.

Taking Monotrim Tablets long term

If you are taking this for a long time, blood tests may be carried out. The doctor may also prescribe an additional drug, folic acid, for you to take.

If you take more Monotrim Tablets than you should

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the container and any remaining tablets with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Monotrim Tablets

If you suffer from a kidney complaint and you forget to take a dose, ask your doctor or pharmacist for advice. Otherwise, if you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Monotrim Tablets

Do not stop just because you feel better. If you stop too soon, the infection may come back. Keep taking the tablets until the prescribed course is finished.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using trimethoprim and seek medical attention immediately if you notice any of the following symptoms:

- 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).
- Difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- Severe itching of the skin, with a red rash or raised lumps.

Seek immediate medical attention if you have any of the following symptoms:

- eye pain, redness, or sensitivity to bright light, blurred vision, floaters (dots that move across the field of vision)
- sudden headache, stiff neck, fever, sensitivity to bright light, drowsiness and muscle pain, with or without a rash
- unusual bleeding or bruising; repeated infections or infections that will not go away. This may be due to changes in your blood. Blood tests may be carried out to check for this
- yellowing of the skin or whites of the eyes with or without a rash caused by liver or blood problems.

Tell your doctor if you get any of the following side effects:

- muscle pain or muscle weakness
- nausea, vomiting or an upset stomach
- reactions to the sun. Skin may become red, painful and swollen - do not sunbathe, use a sun bed, or expose your skin to UV light.

Some people may get an increased amount of potassium in their blood (especially the elderly or those with kidney problems). You cannot feel or see this, but your doctor may test your blood for this side effect.

Other side effects

Very common: may affect more than 1 in 10 people

- High levels of potassium in the blood (hyperkalaemia), particularly in the elderly
- Diarrhoea
- Decreased appetite

Common: may affect up to 1 in 10 people

- Thrush
- Watery diarrhoea, fever, nausea, and abdominal pain (Clostridium difficile infection)
- Headache
- Sore mouth

Very rare: may affect up to 1 in 10,000 people

- Decrease in platelets (blood cells that help you stop bleeding)
- Decrease in red blood cells (anaemia)
- Decrease in the type of white blood cells that help to protect you against infection (neutropenia)
- Increase in eosinophils (a type of white blood cell) in your blood
- Low level of white blood cells (leukopenia)
- Low level of all white blood cells (agranulocytosis)
- Decrease in all cells in your blood (pancytopaenia, bone marrow depression)
- Destruction of red blood cells in your blood (haemolysis)
- Agitation
- Unusual decrease in energy, sleepiness and weakness (lethargy)
- Hallucinations
- Dizziness
- Constipation
- Inflammation of the tongue (glossitis)
- Stomatitis
- Inflammation in your pancreas (pancreatitis)
- Skin reactions, fixed drug eruption

Not known: frequency cannot be estimated from the available data

- Aseptic meningitis. 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
- Decrease in all cells in your blood (depression of haemopoiesis)
- Skin rashes
- Low levels of sodium in the blood, may cause nausea, tiredness, muscle cramping (hyponatraemia)
- Depression
- Anxiety
- Abnormal behaviour
- Confusion
- Sleep difficulties and nightmares
- Involuntary movements
- Tremor
- Poor muscle control that can affect walking and balance (ataxia)
- Syncope
- Feeling of tingling, numbness or “pins and needles” (paraesthesiae)
- Weakness, numbness and pain, usually in the hands and feet (peripheral neuritis)
- Eye redness and pain (uveitis)
- Cough
- Wheezing
- Nosebleeds
- Gastrointestinal upset
- Feeling sick (nausea)
- Being sick (vomiting)
- Changes in liver enzymes (seen in tests)

- Jaundice (yellowing of skin or whites of the eyes)
- Pruritus (itching)
- Rash and redness of the skin
- Hives (urticaria)
- Increased sensitivity of the skin to the sun
- Muscle ache
- Kidney problems (signs may include painful urination or blood in the urine)

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

HPRA Pharmacovigilance
Website: www.hpra.ie

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

5. How to store Monotrim 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 container, label and on the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

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.

6. Contents of the pack and other information

What Monotrim Tablets contain

- The active substance is trimethoprim (100 mg and 200 mg).
- The other ingredients are: potato starch, lactose monohydrate, talc, gelatin, magnesium stearate (see end of Section 2 for further information on lactose).

What Monotrim Tablets look like and contents of the pack

Monotrim 100 mg Tablets are round and white tablets marked AE/2 on one side and with a score line on the reverse.
Monotrim 200 mg Tablets are round and white tablets marked DE/5 on one side and with a score line on the reverse.

They are available in packs of 100 or 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chemidex Pharma Ltd, Vision Exchange Building, Triq it-Territorjals, Zone 1, Central Business District, Birkirkara, CBD 1070, Malta.

Manufacturer

Lelypharma B.V., Zuiveringweg 42, 8243 PZ Lelystad, the Netherlands.

This leaflet was last revised in August 2026.

'Monotrim' is a registered trade mark.