Package leaflet: Information for the patient

Idotrim 100 mg film-coated tablets
Idotrim 160 mg film-coated tablets

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 Idotrim is and what it is used for

Idotrim is used for urinary tract infections, and as preventive treatment for patients with recurrent urinary tract infections.

Idotrim prevents growth of bacteria in urinary tract infection.

Trimethoprim, which Idotrim contains, may also be approved for treatment of other diseases that are not mentioned in this package leaflet. Ask your doctor, pharmacist or other health care professional if you have more questions, and follow their instructions at all times.

2. What you need to know before you take Idotrim

Do not take Idotrim
- if you are allergic to trimethoprim or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant (first 3 months) or might be pregnant
- if you have severely reduced liver function
- if you have a blood disease called blood dyscrasia
- if you have a condition called megaloblastic anaemia.

Warnings and precautions

Talk to your doctor or pharmacist before taking Idotrim:
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking trimethoprim
- if you have a kidney disease or if your kidney function is reduced
- if you have a rare blood problem called porphyria
- if you are elderly or your child is using this medicine in long-term treatment
- if you have a suspected or proven folate deficiency.

Take special care with Idotrim:

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.

Talk to your doctor if you suffer from the following symptoms during the treatment:
- diarrhoea
- sore throat, fever, paleness or red spots on your skin (these can be early signs of disturbance in the blood formation, particularly in prolonged treatment or at high doses).

Concomitant administration of trimethoprim with certain medicines e.g. spironolactone may lead to severe hyperkalaemia (increased potassium blood level). The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.

Other medicines and Idotrim

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:
- warfarin (to prevent blood clotting)
- glibenclamide (to treat diabetes)
- phenytoin (to treat epilepsy)
- cyclosporine (to prevent rejection of transplanted organ)
- antibiotics such as rifampicin, dapsone
- zidovudine (for virus infection, HIV)
- diuretics (water tablets) e.g. spironolactone
- ACE inhibitors (to treat high blood pressure)
- digoxin (to treat heart conditions)
- pyrimethamine (to treat malaria)
- methotrexate (to treat cancer or for your immune system)
- bone marrow depressants.

Trimethoprim may interfere with the assay used to test creatinine in your body.

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.

Pregnancy
This medicine should not be taken during first three months of pregnancy. 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
Idotrim passes into mother’s milk, but is not likely to affect children who are breast-fed. However, consult your doctor in the case of more than occasional use of Idotrim during breast-feeding.

Driving and using machines
Idotrim has no or negligible influence on the ability to drive and use machines.

Idotrim contains lactose
Idotrim 100 mg tablet contains 52.3 mg, 160 mg tablet contains 83.6 mg of lactose (as monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Idotrim

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It is important to complete the prescribed course so that the infection does not flare up again.

The dose is determined by the doctor, who adjusts it individually for you.

Use in adults
The recommended dose for uncomplicated lower urinary tract infection:
- 150–200 mg twice daily, or 300 mg for the night.

The recommended dose in long-term treatment:
- 100 mg for the night.

Use in children and adolescents
The recommended dose for uncomplicated lower urinary tract infection:
- *Children over 3 months:* The dose is determined by the doctor, who adjusts it individually according to the child's weight (age) and condition.
- *Children over 12 years:* 150–200 mg twice daily, or 300 mg for the night.

The recommended dose in long-term treatment:
- *Children over 3 months:* The dose is determined by the doctor, who adjusts it individually according to the child's weight (age) and condition.
- *Children over 12 years:* 100 mg for the night.

The score line is not intended for breaking the tablet.

Use in patients with reduced kidney function
The dose might need to be reduced. It is determined by the doctor and adjusted individually.

If you take more Idotrim than you should
If you have taken more Idotrim than you should, or if children have been taking medicine by accident, please contact your doctor or the hospital to get an opinion of the risk and advice on action to be taken.

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.

Discontinue treatment and contact a doctor or the nearest emergency room if you experience any of the following:
- 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), *may affect up to 1 in 1 000 people)*/ (toxic epidermal necrolysis (TEN), *may affect up to 1 in 10 000 people*).
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome, *frequency cannot be estimated from the available data*).

- swelling in the face, tongue or throat; difficulty swallowing; nettle rash and breathing difficulties (angio-oedema, *may affect up to 1 in 1 000 people*).
- prolonged or severe diarrhoea (bowel inflammation, *may affect up to 1 in 1 000 people*).
- severe widespread skin damage (peeling of outer skin and outer mucous membranes) (*may affect up to 1 in 10 000 people*).

Idotrim may in rare cases affect white blood cells so that immune defence is weakened. If you get an infection with symptoms such as fever with severely worsened general condition or fever with local symptoms of infection, such as pain in the neck/throat/mouth or difficulty urinating, you should immediately see a doctor so that a deficiency of white blood cells (agranulocytosis, *may affect up to 1 in 1 000 people*) can be excluded with blood tests. It is important that you inform them about your medication.

Other side effects that may occur:

Common (*may affect up to 1 in 10 people*): Nausea, vomiting, inflammation of the tongue, itching, skin rash.

Uncommon (*may affect up to 1 in 100 people*): Nettle rash, blood effects (increased or reduced amount of certain blood cells)

Rare (*may affect up to 1 in 1 000 people*): Meningitis, hypersensitivity reactions (such as fever, allergic shock), diarrhoea, sensitivity to sunlight, skin changes (sometimes severe), inflammation of the eye (conjunctivitis), changes in blood count.

Very rare (*may affect up to 1 in 10 000 people*): Serum sickness (e.g. skin rash and swelling, joint pain and swollen glands), inflammation of the eye (uveitis), increased levels of potassium in the blood, hallucinations.

Not known (frequency cannot be estimated from the available data): Low level of a certain type of white blood cells, a disturbance in the bloods ability to absorb oxygen and give off carbon dioxide (methemoglobinemia), change in liver enzyme values in blood tests, cholestasis, yellowish of the skin and eyes (cholestatic jaundice), fungal overgrowth in mouth or genital area.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Idotrim

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

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

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 Idotrim contains

- The active substance is trimethoprim. One tablet contains 100 mg or 160 mg trimethoprim.
- The other ingredients are lactose monohydrate, maize starch, pregelatinised starch, povidone, polysorbate 80, crospovidone, microcrystalline cellulose, magnesium stearate, hypromellose, propylene glycol.

What Idotrim looks like and contents of the pack

100 mg tablets are white, film-coated, round, convex with a score line, with a diameter of 9 mm.
160 mg tablets are white, film-coated, round, convex with a score line, with a diameter of 11 mm.

The score line is not intended for breaking the tablet.

Pack sizes
100 mg tablets: Plastic bottles of 30 and 100 tablets.
160 mg tablets: Plastic bottles of 14, 20 and 100 tablets.

Not all pack sizes may be marketed.

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