

Package leaflet: Information for the Patient

Furaginum US Pharmacia, 50 mg, tablets

Furazidinum

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet, or as your doctor or pharmacist tells you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you experience any adverse effects, including any adverse effects not listed in this leaflet, please inform the doctor or pharmacist. See section 4.
- If there is no improvement after 7-8 days or if you feel worse, consult your doctor.

What is in this leaflet

1. What Furaginum US Pharmacia is and what it is used for
2. What you need to know before you take Furaginum US Pharmacia
3. How to take Furaginum US Pharmacia
4. Possible adverse effects
5. How to store Furaginum US Pharmacia
6. Contents of the pack and other information

1. What is Furaginum US Pharmacia and what is it used for

Furaginum US Pharmacia contains furasidine, also known as furagina, as the active substance. Furasidine is a nitrofuran derivative, which suppresses the growth of Gram-positive and Gram-negative bacteria that cause urinary tract infections.

Furaginum US Pharmacia is indicated for the treatment of:

- treating acute and recurrent uncomplicated infections of the lower urinary tract.

If there is no improvement after 7-8 days or if you feel worse, consult your doctor.

2. What you need to know before you take Furaginum US Pharmacia

Do not take Furaginum US Pharmacia if:

- you are allergic (hypersensitive) to furasidine, other nitrofuran derivatives or any of the other ingredients of Furaginum US Pharmacia.
- you are in the first trimester of pregnancy.
- you are 38 weeks or more pregnant and during labour, as your newborn baby may develop haemolytic anaemia (anaemia associated with breakdown of red blood cells).
- you are a child and adolescent under 15 years of age.
- your kidneys do not work properly and laboratory tests show a creatinine clearance test shows less than 60 ml/min or a high level of creatinine in the serum.
- you have polyneuropathy (disorder of the nervous system), e.g. related to diabetes.
- you have too little glucose-6-phosphate dehydrogenase (an enzyme which takes part in metabolism of red blood cells).

Warnings and precautions

Talk to your doctor before taking Furaginum US Pharmacia if:

- Your kidneys or liver do not work properly, you have problems with a nervous system, anaemia, electrolyte disorders, deficiency of B vitamins and folic acid or lung diseases.
- You have diabetes – furasidine may damage your nerves.
It has been observed that some patients treated with nitrofurantoin derivatives had their peripheral nerves damaged. In severe cases, this disorder may be irreversible and cause death. Therefore, you should stop taking Furaginum US Pharmacia if you notice the symptoms of nervous system problems (tingling, numbness, electric shock sensation).
- If you get fever, chills, cough, chest pain, shortness of breath when taking Furaginum US Pharmacia. These may be symptoms of acute lung reaction sometimes experienced by patients treated with nitrofurantoin derivatives. If you notice these symptoms, stop taking the medicine immediately – the symptoms should then disappear quickly or very quickly. If you take the medicine for a long time, how bad the symptoms are and when they are gone depends on how long you have been treated with the medicine since you noticed the onset of side effects. It is very important to recognise the side effect and stop taking the medicine as soon as possible. Lung problems may be irreversible. Chronic reactions were experienced by patients who used furasidine for more than 6 months. Some patients, especially elderly ones, may suffer from long-time lung problems (including pulmonary fibrosis and disseminated interstitial pneumonia).
- If you have been taking this medicine for a long time, you may need blood tests to check the number of your white blood cells as well as kidney and liver function.
- If you experience severe and persistent diarrhoea during or after treatment. This may be a symptom of pseudomembranous enteritis, a complication which sometimes occurs after taking medicines that suppress the growth of micro-organisms. Contact your doctor immediately and do not take antidiarrhoeal medications that inhibit your bowel movements.

Furaginum US Pharmacia with other medicines

Consult your doctor or pharmacist before taking Furaginum US Pharmacia if you are taking any of the following medicines:

- Nalidixic acid (an antibiotic) – furasidine suppresses its antibacterial effect.
- Aminoglycosides and tetracyclines (antibiotics) – they increase the antibacterial effect of furasidine.
- Chloramphenicol and ristomycin (antibiotics) – they increase the toxic effect of furasidine on blood cells.
- Probenecid (at high doses) and sulfinpyrazone (medicines that increase the elimination of uric acid in urine) – they decrease elimination of furasidine and may cause its accumulation in the body, increasing its toxic effects and decreasing its concentration in the urine; thereby weakening the therapeutic effect of furasidine.
- Medications containing magnesium trisilicate, used to lower the amount of gastric juice – they reduce the absorption of furasidine.
- Atropine – it delays the absorption of furasidine, but the overall absorbed amount does not change.
- B vitamins – they increase the absorption of furasidine.

Effects on laboratory tests

When you take furasidine, the urine glucose test using Benedict's and Fehling's solutions may give false positive result. Yet, the results of urine glucose test performed by enzymatic methods will usually be normal.

Furaginum US Pharmacia with food and drink

Furaginum US Pharmacia should be taken orally with meals containing protein as it increases the absorption of the medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you need to ask your doctor or pharmacist for advice before taking this medicine.

Do not take Furaginum US Pharmacia in the first three months of pregnancy (1st trimester) or from the 38th week and during labour, as furasidine may cause haemolytic anaemia in your baby. Be specially careful if you take Furaginum US Pharmacia in the last three months of pregnancy (3rd trimester).

Do not take Furaginum US Pharmacia while breast-feeding your baby. Furasidine passes into breast milk and may harm the baby.

Driving and using machines

There are no data showing that furasidine may affect the ability to drive and use machines. However, some patients may experience adverse reactions that may affect their ability to drive (dizziness, drowsiness, visual problems).

Furaginum US Pharmacia contains lactose and sucrose

Each tablet contains 18.8 mg lactose and 10 mg sucrose. If the patient has been diagnosed with intolerance to some sugars before, they should contact a doctor before taking this medicine.

3. How to take Furaginum US Pharmacia

Always take this medicine exactly as described in the patient information leaflet or as prescribed by your doctor. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents over 15 years of age

First day of treatment: 2 tablets 4 times daily; subsequent days: 2 tablets 3 times daily.

Furaginum US Pharmacia should be taken with meals containing protein, which increases the absorption of the medicine.

The medicine should be taken for 7-8 days. If after this time the symptoms get worse or do not go away, consult your doctor.

Therapy may be repeated after 10-15 days, if necessary.

Use in children and adolescents

Furaginum US Pharmacia should not be taken by children and adolescents under 15 years of age .

What to do when you overdose on Furaginum US Pharmacia

If you take more Furaginum US Pharmacia than your doctor has recommended, you may notice the following symptoms: headache, dizziness, allergy, nausea, vomiting and anaemia.

If you experience these symptoms, go to the emergency department of the nearest hospital immediately, as you may need specialist treatment (including stomach pumping, intravenous administration of fluids and/or haemodialysis in severe cases). As the medicine is removed from the body through the kidneys, patients with renal impairment are at greater risk of overdose.

What happens if you miss a dose of Furaginum US Pharmacia

If you miss one dose of Furaginum US Pharmacia, skip it and continue with your normal schedule. Do not take a double dose to make up for the missed dose.

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

4. Potential adverse effects

Like all drugs, this medicine can cause side effects, although not everybody will experience them.

The most common side effects observed during clinical trials, most likely related to the use of the medicine, included nausea (8%), headache (6%) and excessive intestinal gas (1.5%). Other symptoms, which are listed below, occurred in no more than 1% of patients; they are listed according to where they happened in the body.

Stop taking this medicine immediately and inform your doctor or go to the nearest hospital if you experience:

- severe skin reactions with scaling or blistering (exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome or bullous erythema multiforme);
- anaphylaxis (a sudden allergic reaction which happens in one place or in the whole body), angioedema (swelling of the dermis and subcutaneous tissue which may cause difficult breathing, most frequently appearing in the face, throat and tongue);
- symptoms of drug-induced hepatitis, cholestatic jaundice (caused by an obstruction in bile outflow), liver necrosis;
- bluish discoloration in the skin, megaloblastic anaemia (vitamin B12 or folate deficiency anaemia) or haemolytic anaemia (caused by excessive breakdown of red blood cells);
- peripheral nerve problems (including acute or irreversible ones, especially if you have a kidney disease, anaemia, diabetes, electrolyte imbalance or vitamin B deficiency);
- infections with furasidine-resistant micro-organisms;
- fever, chills, low self-esteem;
- pancreatitis manifested by severe pain in the upper abdomen;
- pseudomembranous colitis (diarrhoea with crampy pains in your abdomen, slightly raised body temperature; acute inflammation of the colon);

- hypersensitivity reactions in the respiratory tract
 - severe reactions – manifested by fever, chills, cough, chest pains, shortness of breath, abnormal accumulation of fluid in the chest, lung radiographic changes, increased number of a particular type of white blood cell called an eosinophils; they usually disappear quickly or very quickly when the medicine is stopped;
 - chronic reactions – including pulmonary fibrosis and disseminated interstitial pneumonia; how bad the symptoms are and when they are gone depends on how long you have been treated with the medicine since you noticed the onset of side effects; once an adverse reaction is noticed, stop taking the medicine immediately; lung problem may be irreversible;

Other side effects:

- nausea, excessive release of intestinal gas;
- headache.
- dizziness, drowsiness, visual problems;
- constipation, diarrhoea, indigestion (e.g. a feeling of fullness after meals, flatulence), pain in your abdomen, vomiting, inflammation of salivary glands;
- hair loss;
- irritating sensation, urticaria, rash.

Nitrofurantoin derivatives may have a negative effect on your testis and decrease sperm motility, decrease sperm secretion and lead to severe changes in sperm structure.

Reporting of side effects

If you notice any side effects, including any side effects not listed in this leaflet, talk to your doctor or pharmacist. Any side effects may be reported directly to the Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products [*Departament Monitorowania Niepożądaných Działání Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych*]

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Side effects may be reported also to the Marketing Authorisation Holder.

By reporting side effects, you can help provide more information about the safe use of the medicine.

5. How to store Furaginum US Pharmacia

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the blister and on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist what to do with medicines you no longer use. These measures will help protect the environment.

6. Other information

What does Furaginum US Pharmacia contain

The active substance of the medicine is furasidine, also called furagina. 1 tablet contains 50 mg of furasidine.

Other ingredients of the medicine are: lactose, gelled starch, sucrose, polysorbate 80, stearic acid.

What Furaginum US Pharmacia looks like and contents of the pack

Uncoated tablets, flat on both sides, with yellow-orange colour.

Fol containing 30 tablets in blister packs.

Marketing Authorisation Holder

US Pharmacia Sp. z o.o.

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Manufacturer

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For more information, please contact a representative of the Marketing Authorisation Holder:

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