Package leaflet: Information for the user

Nitrofurantoin 50 mg Tablets
Nitrofurantoin 100 mg Tablets

Nitrofurantoin

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

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

1. What Nitrofurantoin Tablets is and what it is used for

Nitrofurantoin (the active substance in Nitrofurantoin Tablets) is an antibiotic.
It is used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract.

You must talk to a doctor if you do not feel better or if you feel worse.

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

Do not take Nitrofurantoin Tablets:
• if you are **allergic** to Nitrofurantoin, other medicines containing nitrofurantoin or any of the other ingredients of this medicine (listed in Section 6)
• if you have a **disease of the kidneys** which is severely affecting the way they work (ask your doctor if you are not sure)
• if you are in the final stages of **pregnancy** (labour or delivery) as there is a risk that it might affect the baby
• if you have porphyria (**blood disorder**)
• if you are a patient with G6PD (glucose-6-phosphate dehydrogenase) deficiency
• if your **child** is under three months of age
• if you are breast-feeding a baby with suspected or known deficiency in an enzyme called G6PD (glucose-6-phosphate dehydrogenase).

Tell your doctor if you are not sure about any of the above.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Nitrofurantoin Tablets:
• if you have **diabetes**
• if you are suffering from any illness causing **severe weakness**
• if you have **anaemia** (a decrease in red blood cells causing pale skin, weakness and breathlessness) or a lack of vitamin B or abnormal levels of salts in your blood (your doctor will

be able to advise you)
• if you have a history of **allergic reactions**
• if you have any **problems with your kidneys**.
• if you have disease of the lungs
This medicine can also cause lung disease in patients with no previous medical history affecting their lungs. Lung disease can occur in patients on short-term or long-term treatment. Talk to your doctor if you experience trouble breathing, shortness of breath, a lingering cough, coughing up blood or mucus, or pain or discomfort when breathing. These may be symptoms of side effects affecting the lungs.

The above conditions may increase the chance of developing a side effect which results in damage to the nerves, causes altered sense of feeling, pins and needles.
• if you lack an enzyme (body chemical) called glucose-6-phosphate dehydrogenase, which causes your **red blood cells** to be more easily damaged (this is more common in black people and people of Mediterranean, Middle Eastern or Asian origin. Your doctor will know)
• if you have any **disease of the lungs, liver or nervous system**. If you need to take Nitrofurantoin Tablets for a number of months, your doctor may want to regularly check how your lungs and liver are working

• as this medicine may interfere with urine tests for glucose, causing the test to give a "false positive" result. That is, the test may say that glucose is present in the urine even if it is not.
This medicine may also cause your urine to turn yellow or brown.

• if you experience fatigue, yellowing of the skin or eyes, itching, skin rashes, joint pain, abdominal discomfort, nausea, vomiting, loss of appetite, dark urine, and pale or gray-colored stools. It may be symptoms of liver disorder.

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

If they are taken with Nitrofurantoin Tablets their effect or the effect of Nitrofurantoin Tablets may be changed.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
• Antacids for indigestion (e.g. magnesium trisilicate)
• Medicines for gout (e.g. probenecid or sulfinpyrazone)
• Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine)
• Medicines for raised pressure in the eye (glaucoma), such as carbonic anhydrase inhibitors (e.g. acetazolamide)
• Medicines which make the urine less acidic (e.g. potassium citrate mixture)
• Medicines for infections, known as quinolones
• Typhoid vaccine, which is given for the prevention of typhoid.

If you are in doubt about any of these medicines ask your doctor or pharmacist.
Nitrofurantoin Tablets may interfere with the results of some tests for glucose in the urine.

Nitrofurantoin Tablets with food and drink
Nitrofurantoin Tablets should always be taken with food or milk. Taking this medicine with food or milk makes it work more effectively. This will help to avoid stomach upset and also to help the absorption.

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.

As far as is known, Nitrofurantoin Tablets may be used in pregnancy. However, it should not be used during labour or delivery because there is a possibility that use at this stage may affect the

baby. If you want to breast-feed, please consult your doctor first.

Driving and using machines
Nitrofurantoin Tablets may cause dizziness and drowsiness. You should not drive or operate machinery if you are affected this way until such symptoms go away.

Nitrofurantoin Tablets contain lactose
This medicine contains lactose (sugars). 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 Nitrofurantoin 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.

The recommended dose is:
Adults:
The normal dosage depends on the type of infection you have and instructions should be written on the label provided by the pharmacist. Consult your pharmacist or doctor if these instructions are not clear. The usual doses are:
• For treatment of infections: Either one 50mg tablet or one 100mg tablet four times a day for seven days
• For prevention of further infections: Either one 50mg tablet or one 100mg tablet at bedtime
• For prevention of infections during surgery: One 50mg tablet four times a day on the day of the operation and three days thereafter.

Use in children over three months of age:
The dose depends on the weight of the child and will be provided by your doctor. Follow your doctor's instructions exactly.

Children below 3 months of age should not take Nitrofurantoin Tablets

Medical Checks
Your doctor will watch carefully for any effects on the liver, lungs, blood or nervous system. Nitrofurantoin Tablets may interfere with the results of some tests for glucose in the urine.

Method of administration
Tablets should be swallowed whole. The score line is not intended for breaking the tablet.

Nitrofurantoin Tablets should always be taken with food or milk. Taking this medicine with food or milk makes it work more effectively.

If you take more Nitrofurantoin Tablets than you should
Consult your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any left-over tablets with you, as well as the container and label, so that the medical staff knows what you have taken. You may experience symptoms of stomach ache, nausea and vomiting.

If you forget to take Nitrofurantoin Tablets
Do not worry. If you remember later on that day, take that day's dose as usual. If you miss a whole day's dose take the normal dose on the next day. Do not take a double dose to make up for a forgotten dose. If you are not sure ask your doctor or pharmacist.

If you stop taking Nitrofurantoin Tablets
Your doctor will tell you how long to take the treatment. Do not stop earlier than you are told, even if you feel better.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of them are mild and disappear when you stop taking Nitrofurantoin Tablets.

All medicines can cause allergic reactions although serious allergic reactions are rare. If you notice any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) STOP TAKING your medicine and go to a doctor immediately.

If you experience any of the side effects detailed below, stop taking Nitrofurantoin Tablets and consult your doctor.
•Your lungs may react to Nitrofurantoin Tablets. This can happen quickly, within one week after the start of treatment, or very slowly, especially in the elderly and can lead to fever, chills, cough and shortness of breath associated with pneumonia. Scaring due to damage lung tissue may occur.
• Jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes)
• The nerves outside the spinal cord may be affected causing changes to the sense of feeling and the use of muscles. In addition headache, extreme changes of mood or mental state, confusion, weakness, involuntary eye movement (which may cause the eye to rapidly move from side to side, up and down or in a circle, and slightly blur vision) may occur. These effects may be severe and in some instances
permanent
• Raised pressure in the skull (causing severe headaches)
• Severe reduction in blood cells which can cause weakness, bruising or make infections more likely
• Blue or purple coloration of the skin due to low oxygen levels. A condition known as cyanosis
• Symptoms of fever, flu, abdominal pain, diarrhea, blood in your stool and weakness. These could be signs of a condition known as cutaneous vasculitis
• Symptoms of jaundice, fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as autoimmune hepatitis.

Please note that while taking Nitrofurantoin Tablets your urine may become dark yellow or brown coloured. This is quite normal and not a reason to stop taking the medicine.

Other side effects include:

Rare (may affect up to 1 in 1,000 people)
• Loss of consciousness (collapse)
• Damage to bone marrow causing deficiency of the red blood cells (Anaemia)

Not known (frequency cannot be estimated from the available data)
• Feeling sick (nausea) and headache
• Loose stools
• Loss of appetite, stomach ache, and being sick (vomiting)

• Dizziness, drowsiness
• Blood cells have been affected in some patients. This may result in bruising, delayed clotting of the blood, sore throat, fever, anaemia, and a susceptibility to colds or persistent cold
• A variety of skin rashes or reactions have occurred in some patients. These may appear as flaking skin, a red rash or fever accompanied by rapid heart rate and severe rash with blistering. Other reactions may include inflammation of salivary glands (causing facial pains), inflammation of the pancreas gland (causing severe abdominal pain) and joint pains
• Short-term hair loss
• Urinary infection by germs which are not sensitive to Nitrofurantoin Tablets.
• Inflammation of small blood vessel walls, causing skin lesions

• Liver inflammation due to turn of immune system against liver cells
• Inflammation of kidney tissue surrounding tubules, causing renal impairment

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 MHRA yellow card scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Nitrofurantoin 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 carton and label. The expiry date refers to the last day of that month.

This product does not require any special storage conditions.

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 Nitrofurantoin Tablets contains

The active substance is Nitrofurantoin. Nitrofurantoin Tablets are available in two strengths, containing either 50 mg or 100 mg Nitrofurantoin.

Nitrofurantoin Tablets are available in PVC – Aluminium blisters containing 20, 28, 30, 50 or 100 tablets.

The other ingredients are maize starch, lactose monohydrate, magnesium stearate and polyvidone
What Nitrofurantoin Tablets looks like and contents of the pack

50 mg Tablet
Yellow, round, biconvex tablets with a single score line on one side, approximately 8.0 mm ± 0.2 mm in diameter.
The score line is not intended for breaking the tablet.

100 mg Tablet
Yellow, round, biplane with bevelled edge tablets with a single score line on one side and debossed “I” on the other side, approximately 10.0 mm ± 0.2 mm in diameter.
The score line is not intended for breaking the tablet.

Marketing Authorisation Holder

Glenmark Pharmaceuticals Europe Limited
Laxmi House
2-B Draycott Avenue
Kenton
Middlesex
HA3 0BU
United Kingdom

Manufacturer
IASIS Pharmaceuticals Hellas ABEE
137 Filis Ave
Kamatero Attiki
13451, Greece

IASIS Pharmaceuticals Hellas ABEE – KOROPI
Archimidous str.
Koropi Attikis
19400, Greece

This leaflet was last revised in

May 2026