

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Nitrofurantoin 50 mg & 100 mg tablets

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 4.

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 are and what they are used for

Nitrofurantoin (the active ingredient) 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 your 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 breastfeeding 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.

The above conditions may increase the chance of developing a side effect which results in damage to the nerves, causes altered sense of feeling like 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
- if you have false positive results on testing your urine for glucose
- if your urine is dark yellow or brown coloured.

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.

Talk to your doctor 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 grey coloured 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 including medicines obtained without a prescription. 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 with food and drink

Taking this medicine with food or milk makes it work more effectively.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, 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 breastfeed, 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 medicinal product.

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.

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 leftover tablets with you, as well as the container and label, so that the medical staff know 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, shivering, coughing and shortness of breath associated with pneumonia and/or tissue damage.
- jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes)

- the nerves outside of 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, blurred 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, diarrhoea, 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 coloured dark yellow or brown. 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).

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)
- diarrhoea
- dizziness, drowsiness
- sensation that you or your environment are moving or spinning (vertigo)
- unusual eye movements (nystagmus)
- 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 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.

This product does not require any special storage conditions. Do not use this medicine after the expiry date which is stated on the carton after 'EXP (mm/yy)'. 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 Nitrofurantoin tablets contain

The active substance is nitrofurantoin. Each tablet contains either 50mg or 100mg of nitrofurantoin. The other ingredients are maize starch, lactose monohydrate, magnesium stearate, povidone K 30.

What Nitrofurantoin tablets look like and contents of the pack

Nitrofurantoin 50 mg tablets are yellow, round, biconvex tablets of 8.0 mm \pm 0.2 mm diameter and 3.5 mm \pm 0.3 mm thickness with a single score line on one side.

Nitrofurantoin 100 mg tablets are yellow, round, biplane with bevelled edge tablets of 10.0 mm \pm 0.2 mm diameter and 4.0 mm \pm 0.3 mm thickness with a single score line on one side and debossed "T" on the other side.

Both 50 mg and 100 mg strengths are available in blister packs of 28 and 100 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mylan,
Potters Bar,
EN6 1TL,
United Kingdom

Manufacturer

IASIS Pharmaceuticals Hellas S.A
137, Filis Ave.
Kamatero, Attiki, 13451
Greece

IASIS Pharmaceuticals Hellas S.A-Koropi
Archimidous Street,
Koropi Attikis, 19 400,
Greece

Mylan UK Healthcare Limited,
Building 20,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom

This leaflet was last revised in May 2023