

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER  
Nitrofurantoin 50mg & 100mg  
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 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 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.

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

**Do not take Nitrofurantoin Tablets and talk to your doctor if:**

- you are allergic (causing itching, reddening of the skin or difficulty in breathing) to nitrofurantoin or any of the other ingredients (listed in Section 6 at the end of the leaflet) or other medicines containing nitrofurantoin.
- you have a disease of the kidneys which is severely affecting the way they work (ask your doctor if you are not sure)
- you are in the final stages of pregnancy (labour or delivery) as there is a risk that it might affect the baby
- you have porphyria (blood disorder)
- you have G6PD (glucose-6-phosphate dehydrogenase) deficiency
- in infants under three months of age
- 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 or pharmacist before taking Nitrofurantoin Tablets if:

- you have diabetes
- you are suffering from any illness causing severe weakness
- you have anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness) or a lack of vitamin B (particularly folate) or abnormal levels of salts in your blood (your doctor will be able to advise you)
- you have a history of allergic reactions.

The above conditions may increase the chances of developing a side effect which results in damage to the nerves, causes altered sense of feeling and pins and needles.

- you lack an enzyme (body chemical) called glucose-6-phosphate dehydrogenase which causes your red blood cells to become more easily damaged (this is more common in black people and people of Mediterranean, Middle Eastern or Asian origin. Your doctor will know)
- 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
- you have false positive results on testing your urine for glucose
- your urine is dark yellow or brown coloured.

**Children**

**Do not give Nitrofurantoin Tablets to infants under 3 months of age.**

**Other medicines and Nitrofurantoin Tablets**

Please 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.

- 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 acid (e.g. potassium citrate mixture)
- Medicines for infections, known as quinolones
- Oral contraceptives "the pill". You will need to use extra contraceptive precautions such as using a condom, as antibiotics can make the contraceptive pill less effective
- 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 may interfere with the results of some tests for glucose in the urine.

**Nitrofurantoin Tablets with food and drink**

Nitrofurantoin Tablets should be taken at meal times with food or milk. This will help to avoid stomach upset and also to help the absorption.

**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any 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. If you have been told by your doctor that you are intolerant to some sugars and have to avoid them, contact your doctor before taking this medicine.

**3. How to take Nitrofurantoin Tablets**

Follow your doctor's instructions exactly and **complete the course of treatment even if you feel better**. You should check with your doctor or pharmacist if you are not sure. Do not forget to take your medicine. Tablets should be swallowed whole.

**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:**

**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.

**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.

**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 tablet. 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 product, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Nitrofurantoin Tablets 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 may develop quickly, within a week of starting treatment or very slowly, especially in elderly patients. This may produce fever, chills, cough and shortness of breath.
- 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).

**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:**

- 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 infections by germs that are not sensitive to Nitrofurantoin Tablets.

**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 Yellow Card Scheme, website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Nitrofurantoin Tablets**

**Keep out of the sight and reach of children.** Do not store above 25°C. Do not open the container until you are ready to begin taking the course of treatment. Do not use after the expiry date which is stated on the bottle/label after 'Exp (MM/YY)'. 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 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 (which makes the medicine work) is Nitrofurantoin. Each tablet contains either 50mg or 100mg of nitrofurantoin. The other ingredients are: lactose, maize starch, pregelatinised maize starch, sodium starch glycollate and magnesium stearate.

**What Nitrofurantoin Tablets look like and contents of the pack**

Nitrofurantoin Tablets are flat, round bevelled, yellow scored tablets. Both 50 mg and 100 mg strengths are available in containers and blister packs of 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1,000 tablets.

**Marketing Authorisation Holder and Manufacturer**

Dr. Reddy's Laboratories (UK) Ltd, 6 Riverview Road, Beverley, HU17 0LD

Nitrofurantoin 50mg Tablets PL 08553/0087  
Nitrofurantoin 100mg Tablets PL 08553/0088

Leaflet last revised: June 2013 © Dr. Reddy's Laboratories (UK) Ltd  
PC 181  
150049464