

**PACKAGE LEAFLET**

**Package leaflet: Information for the patient**  
**Nitrofurantoin 50mg and 100mg Capsules, Hard**

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

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

Nitrofurantoin 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**

**Do not take Nitrofurantoin if:**

- you are allergic to nitrofurantoin, nitrofurans or any of the other ingredients of this medicine (listed in section 6);
- you have a disease of the kidneys, which is severely affecting the way that they work;
- you are in the final stages of pregnancy (labour or delivery), as there is a risk that this medicine might affect the baby;
- you suffer from a blood disorder called porphyria;
- you are deficient in an enzyme called G6PD (glucose-6-phosphate dehydrogenase);
- your child is under three months of age and has been prescribed this medicine;
- you are breast feeding a baby who has a suspected or a known G6PD (glucose-6-phosphate dehydrogenase) enzyme deficiency.

**Warnings and precautions**

**Talk to your doctor or pharmacist before taking Nitrofurantoin if:**

- you have diabetes;
- you are suffering from any illness which is causing severe weakness;

- you have anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness), a lack of vitamin B or abnormal levels of salts in your blood (your doctor will be able to advise you);
- you have a history of allergic reactions;
- you have any problems with your kidneys.

The above conditions may increase the chance of developing side effects which result in damage to the nerves, causing an altered sense of feeling or pins and needles.

- 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 people of black skin, or Mediterranean, Middle Eastern or Asian origin);
- 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.

- you have any disease of the liver or nervous system. If you need to take Nitrofurantoin for a number of months, your doctor may want to regularly check how your lungs and liver are working;
- this medicine interferes 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.

- 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**

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, their effect or the effect of Nitrofurantoin 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 increased 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 known as quinolones (used to treat infections).
- 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 with food and drink:**

Nitrofurantoin 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 aid 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 it is known, Nitrofurantoin may be used in pregnancy.

However, Nitrofurantoin should not be used during labour or delivery because there is a possibility that taking this medicine at this stage may affect the baby.

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

### **Driving and using machines:**

Nitrofurantoin may cause dizziness and drowsiness. You should not drive or operate machinery if you are affected in this way.

### **Nitrofurantoin contains lactose**

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**

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

The recommended dose is:

### **Adults:**

The normal dose depends on the type of infection you have, and instructions should be written on the label provided by the pharmacist. Consult your doctor or pharmacist if these instructions are not clear.

The usual doses are:

- For treatment of infections: Either one 50mg capsule or one 100mg capsule four times a day for seven days.
- For prevention of further infections: Either one 50mg capsule or one 100mg capsule at bedtime.
- For prevention of infections during surgery: One 50mg capsule four times a day on the day of the operation and for three days after.

### **Use in children and infants 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 under 3 months of age should not take Nitrofurantoin.**

### **Medical Checks:**

Your doctor will monitor you carefully for any effects on the liver, lungs, blood or nervous system.

Nitrofurantoin may interfere with the results of some tests for glucose in the urine.

### **Method of administration**

Nitrofurantoin 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 than you should:**

If you accidentally take more Nitrofurantoin capsules than you should, contact your doctor or nearest hospital emergency department immediately for advice. Take any remaining capsules and this leaflet with you, so that the medical staff know what you have taken.

**If you forget to take Nitrofurantoin:**

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose.

**If you stop taking Nitrofurantoin:**

Do not stop taking Nitrofurantoin without talking to your doctor. Your doctor will tell you how long to take this medicine for. Do not stop sooner than you have been told, even if you feel better.

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. Most of them are mild and disappear when you stop taking Nitrofurantoin.

**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 see a doctor immediately.**

**If you notice any of the following side effects consult your doctor immediately:**

Problems with your lungs. 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.

**If you experience any of the side effects detailed below stop taking Nitrofurantoin and consult your doctor.**

- 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 lightly 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 colouration 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 capsules, 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 a 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 (causing severe abdominal pain) and joint pains
- short-term hair loss
- urinary infection caused by germs which are not sensitive to Nitrofurantoin
- 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 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 at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search 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**

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 after 'EXP'. 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 dispose of medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Nitrofurantoin Capsules contain**

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

The other ingredients are: lactose monohydrate, pregelatinised starch, talc. The capsule shell contains gelatin, quinoline yellow (E104), iron oxide yellow (E172) and titanium dioxide (E171). The printing ink contains shellac, propylene glycol, potassium hydroxide and black iron oxide (E172).

### **What Nitrofurantoin Capsules look like and contents of the pack**

The 50mg capsule is a yellow and white capsule with “EM28” printed on it in black ink. It also has a black band printed around it.

The 100mg capsule is a yellow capsule with “EM29” printed on it in black ink. It also has a black band printed around it.

Nitrofurantoin Capsules are available in blister packs of 20 and 30 capsules.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Tillomed Laboratories Ltd  
220 Butterfield  
Great Marlings  
Luton, LU2 8DL  
United Kingdom

#### **Manufacturer<sup>1</sup>**

Tillomed Laboratories Ltd  
220 Butterfield  
Great Marlings  
Luton, LU2 8DL  
United Kingdom

MIAS Pharma Limited  
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Ireland

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<sup>1</sup>Only actual manufacturer stated on printed leaflet.