

Package leaflet: Information for the patient

## Nitrofurantoin 50 mg and 100 mg 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, 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 Capsules are and what they are used for
2. What you need to know before you take Nitrofurantoin Capsules
3. How to take Nitrofurantoin Capsules
4. Possible side effects
5. How to store Nitrofurantoin Capsules
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### 1. What Nitrofurantoin Capsules are and what they are used for

Nitrofurantoin (the active substance in Nitrofurantoin Capsules) 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 Capsules

#### Do not take Nitrofurantoin Capsules:

- if you are allergic (causing itching, reddening of the skin or difficulty in breathing) to nitrofurantoin or any of the ingredients of Nitrofurantoin Capsules (listed in Section 6 at the end of the leaflet) or other medicines containing nitrofurantoin.
- 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 suffer from a blood disorder called porphyria
- if you are deficient in an enzyme called G6PD (glucose-6-phosphate dehydrogenase)
- 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 Capsules:

- 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, 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 Capsules 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 grey-coloured stools. It may be symptoms of liver disorder.

#### Other medicines and Nitrofurantoin Capsules

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If they are taken with Nitrofurantoin Capsules their effect or the effect of Nitrofurantoin Capsules 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
- Oral contraceptive "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 Capsules may interfere with the results of some tests for glucose in the urine.

**Nitrofurantoin Capsules with food and drink**  
Nitrofurantoin Capsules 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, breast-feeding and fertility

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

#### Nitrofurantoin Capsules contains lactose

This medicine contains lactose. If you have been told by your doctor that you are intolerant to lactose and have to avoid them, contact your doctor before taking this medicine.

#### Nitrofurantoin Capsules contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### 3. How to take Nitrofurantoin Capsules

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

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

**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.

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### Children below 3 months of age should not take Nitrofurantoin.

For children > 3 months and under 6 years of age or under 25 kg body weight, other, more suitable formulations should be used.

#### Medical Checks:

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

#### Method of administration

Nitrofurantoin Capsules 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 Capsules than you should

Consult your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any leftover capsules with you, as well as the container and label, so that the medical staff knows what you have taken.

### If you forget to take Nitrofurantoin Capsules

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 capsule. If you are not sure ask your doctor or pharmacist.

### If you stop taking Nitrofurantoin Capsules

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

**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 Capsules and consult your doctor.

- Your lungs may react to Nitrofurantoin Capsules. 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 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, skin lesions 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)
- Liver failure (which may be fatal).

- **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 (causing severe abdominal pain) and joint pains.
- Short-term hair loss
- Urinary infection by germs which are not sensitive to Nitrofurantoin Capsules
- 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
- Pulmonary fibrosis; possible association with lupus erythematosus
- Depression, euphoria (feeling high), psychosis
- Vertigo
- Nystagmus (explained).

#### 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:

HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)  
By reporting side effects you can help provide more information on the safety of this medicine.

### 5. How to store Nitrofurantoin capsules

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

This medicinal product does not require any special storage conditions.  
Do not use Nitrofurantoin Capsules after the expiry date which is stated 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 how to dispose of medicines no longer required. These measures will help to protect the environment.

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

#### What Nitrofurantoin Capsules contains:

The active substance is nitrofurantoin. Nitrofurantoin Capsules are available in two strengths, containing either 50 mg or 100 mg nitrofurantoin.  
The other ingredients are talc, maize starch, lactose monohydrate. The capsule shell contains gelatin, sodium lauryl sulphate and titanium dioxide (E171). The printing ink contains shellac and black iron oxide (E172) or red iron oxide (E172).

#### What Nitrofurantoin Capsules looks like and contents of the pack

The 50 mg capsule is a hard gelatin capsule of Size "2" with white opaque cap marked "NF 50" with red colour and white opaque body marked "NF 50" with red colour and 360 degree red colour band on cap and body containing pale yellow to yellow granular powder.

The 100 mg capsule is a hard gelatin capsule of Size "2" with white opaque cap marked "NF 100" with black colour and white opaque body marked "NF 100" with black colour and 360 degree black colour band on cap and body containing pale yellow to yellow granular powder.

The capsules are available in blister pack of 30 and HDPE bottle packs of 500's and 1000's.

#### Marketing Authorisation Holder

Azure Pharmaceuticals Ltd, 12 Hamilton Drive, The Rock Road, Blackrock, Co. Louth, A91 T997, Ireland.

#### Manufacturer

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