

## Package leaflet: Information for the user

### Nitrofurantoin 50 mg Capsules Nitrofurantoin 100 mg Capsules

Nitrofurantoin in macrocrystalline form

**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 Capsules is and what it is 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
6. Contents of the pack and other information

#### 1. What Nitrofurantoin Capsules is and what it is 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.

#### 2. What you need to know before you take Nitrofurantoin Capsules

##### Do not take Nitrofurantoin Capsules:

- if you are **allergic** to nitrofurantoin, other medicines containing nitrofurantoin or to any of the 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 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 or pharmacist 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, causing altered sense of feeling such as 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 East 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

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.

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.

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 gray-colored stools. It may be symptoms of liver disorder.

### **Other medicines and Nitrofurantoin Capsules**

Tell your doctor or pharmacist if you are taking, have recently or might take 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
- 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 with food and drink**

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

### **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**

One 50 mg capsule contains 103.50 mg lactose.

One 100 mg capsule contains 207 mg lactose.

This should be taken into account in patients with lactose intolerance.

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 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.

#### **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 the 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.

#### **Use in children and infants aged over three months of age:**

The dose depends on the weight of the child and will be provided by your doctor. Follow your doctor instructions exactly. For children > 3 months and under 6 years of age or under 25 kg body weight, other, more suitable formulations should be used.

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

#### **Medical Checks:**

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

#### **How to take this medicine:**

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

#### **If you take more Nitrofurantoin Capsules you should:**

Consult your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any left over capsules 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 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 reaction 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.**

- 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.
- 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, 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.
- 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 fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as hepatitis.

**Other side effects include:**

**Rare (may affect up to 1 in 1,000 people)**

- Loss of consciousness (collapse)
- Blue or purple coloration of the skin due to low oxygen levels. A condition known as cyanosis.
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely. A condition known as aplastic anaemia.

**Not known (frequency cannot be estimated from the available data)**

- Feeling sick (nausea) and headache
- Diarrhoea
- Loss of appetite, stomachache, 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 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
- Jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes).
- Confusion
- Depression
- Very happy (euphoria)
- Psychotic reactions
- Urine may become coloured dark yellow or brown coloured. This is quite normal and not a reason to stop taking the medicine.

### **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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 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 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 in macrocrystalline form.

Nitrofurantoin Capsules are available in two strengths, containing either 50 mg or 100 mg nitrofurantoin.

#### **The other ingredients are**

50 mg capsules:

maize starch, lactose monohydrate, talc, titanium dioxide, yellow iron oxide, gelatin

100 mg capsules:

maize starch, lactose monohydrate, talc, titanium dioxide, yellow iron oxide, gelatin

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

Nitrofurantoin 50 mg capsule is hard gelatin capsule with yellow cap and white body with dimensions:

Length approximately 16 mm and diameter approximately 6 mm.

Nitrofurantoin 100 mg capsule is hard gelatin capsule with yellow cap and body with dimensions:

Length approximately 19 mm and diameter approximately 7 mm.

The capsules are available in PVC/aluminium blister packs of 30.

**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 S.A. – KOROPI

Archimidous Street

Koropi Attikis

19 400, Greece

**This leaflet was last revised in June 2023**