

**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.

## **NIFURAN capsules, hard 50 mg** *Nitrofurantoin*

In this leaflet:

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**1. What NIFURAN is and what it is used for**  
**NIFURAN** (nitrofurantoin is an antibiotic. It is used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract.

### **2. Before you take NIFURAN** **Do not take NIFURAN 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 **NIFURAN** 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 **NIFURAN** capsules 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 **NIFURAN** capsules to infants under 3 months of age.

### **Other medicines and NIFURAN capsules**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If they are taken with **NIFURAN** their effect or the effect of **NIFURAN** capsules 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
- 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.

### **Nifuran with food and drink NIFURAN**

capsules 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 **NIFURAN** 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**

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

### **Other informations**

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 NIFURAN**

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.  
Capsules 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 or two 50 mg capsules four times a day for seven days.

**For prevention of further infections:** Either one or two 50mg capsules at bedtime.

**For prevention of infections during surgery:** One 50mg capsule four times a day on the day of the operation and three days after.

### **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 NIFURAN capsules.**

#### Medical checks

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

#### If you TAKE MORE NIFURAN 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 NIFURAN

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 NIFURAN

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, **NIFURAN** can cause side effects, although not everybody gets them. Most of them are mild and disappear when you stop taking **NIFURAN**. 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 **NIFURAN** and consult your doctor.

Your lungs may react to **NIFURAN**. 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 **NIFURAN** 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 **NIFURAN**.

#### 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.

#### 5. How to store NIFURAN

Store **NIFURAN** below 25°C. Keep this medicine in a safe place where children cannot see or reach it!

#### Shelf life

2 years. The expiry date of the drug is indicated on the package. The expiry date refers to the last day of that month.

#### 6. Further information

##### Content

**NIFURAN** hard capsules 50 mg  
Each capsule contains 50 mg of nitrofurantoin as active substance

Excipients: lactose monohydrate, sodium lauryl sulfate, colloidal silicon dioxide, magnesium stearate

##### Contents of the pack

30 (3x10) capsules 50 mg in a blister pack, in a box.

##### Anatomical Therapeutic Chemical Classification System-(ATC): J01XE01

##### Marketing Authorisation Holder and Manufacturer

ZADA Pharmaceuticals Ltd.

Donji Bistarac without number

75300 Lukavac, Bosna i Hercegovina.

##### Classification:

Prescription only.

Additional information can be obtained from your doctor or pharmacist, who have more detailed information about **NIFURAN** and your health.

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Capsules 30x50 mg

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