

PACKAGE LEAFLET: INFORMATION FOR THE USER

NIFURAN

50 mg capsules

NITROFURANTOIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What NIFURAN is and what it is used for
2. Before you take NIFURAN
3. How to take NIFURAN
4. Possible side effects
5. How to store NIFURAN

1. WHAT NIFURAN IS AND WHAT IS IT 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. BEFORE YOU TAKE NIFURAN

Do not take NIFURAN Capsules 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 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 Capsules 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.
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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 Capsules 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
- 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.

NIFURAN Capsules 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.

NIFURAN Capsules 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 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: one or two 50mg Capsules four times a day for seven days.

For prevention of further infections: 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 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 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 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 know what you have taken.

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

- Your lungs may react to NIFURAN 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 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 Capsules 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 Capsules.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NIFURAN

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.