Package Leaflet: Information for the User

Nitrofurantoin 50 mg hard capsules

Nitrofurantoin 100 mg hard capsules

nitrofurantoin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further question, 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 symptoms 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

Nitrofurantoin (the active substance in Nitrofurantoin Capsules) is an antibiotic. It is used to treat and prevent infections of the urinary tract and bladder.

You must talk to a doctor if you do not feel better or if you feel worse during or after treatment.

2. What you need to know before you take Nitrofurantoin

DO NOT TAKE Nitrofurantoin

- If you are allergic to nitrofurantoin or any of the ingredients of this medicine (listed in Section 6)
- If you are allergic to other nitrofuran
- If you have been advised by your doctor that you have a low kidney function (eGFR less than 45ml per minute)
- If you are in the final stages of pregnancy (labour or delivery)
- In babies under three months of age
- 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 know that you have a condition called porphyria group of blood disorders that affect the nervous system or skin, or both
- If you have had a reaction in your lung, liver or nerves (peripheral neuropathy) after taking nitrofurantoin or other nitrofurans.

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 if:

- you have diabetes
- you have kidney problems, as you may require additional monitoring by your doctor during treatment
- you have symptoms of numbness or weakness in the extremities (peripheral neuropathy)
- 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)
- you have a history of allergic reactions

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 have any disease of the lungs, liver or nervous system.
- If you need to take Nitrofurantoin for a number of months, especially if you are elderly, 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.
- If you have diarrhoea caused by a bacteria known as clostridium difficile
- If you are taking any other antibacterial medicines.
- 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.
- This medicine may interfere with urine tests for glucose, causing the test to give a “false positive” result.

Some black people and people of Mediterranean, Near Eastern or Asian origin may develop anaemia during treatment. If you belong to this group and you develop tiredness, dizziness and shortness of breath during treatment, stop taking the medicine and contact your doctor

Other medicines and Nitrofurantoin:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If the following medicines are taken with Nitrofurantoin their effect or the effect of Nitrofurantoin may be changed:

• Magnesium trisilicate (an antacids used for indigestion)
• Medicines for gout (e.g. probenecid or sulfinpyrazone)
• Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine)
• Medicines for glaucoma: such as carbonic anhydrase inhibitors (e.g. acetazolamide).
• Medicines known as urine alkalizing agents which make the urine less acid (e.g. potassium citrate mixture)
• Medicines for infections, known as quinolones
• Typhoid vaccine when taken by mouth.

Nitrofurantoin with food and drink:

Nitrofurantoin should be taken with food or milk. This will help to avoid stomach upset and also to help the 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 any medicine.

Pregnancy
As far as it is known, nitrofurantoin 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 (see "DO NOT TAKE" section above).

Breastfeeding
If you wish to breastfeed, consult your doctor first because this medicine passes into breast milk and may pose a hazard to infants under 3 months of age or infants lacking a certain enzyme (body chemical).

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

Nitrofurantoin contain lactose and sodium:
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Nitrofurantoin

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

Follow your doctor's instructions exactly and complete the course of treatment even if you feel better.

Recommended Dose

Adults and children over 10 years of age:
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 50mg capsule four times a day for seven days
• For treatment of severe chronic recurrent infections: 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 thereafter.

Use in children and infants over 3 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.
The use of this medicine (a capsule) may not be suitable for younger children. Other forms of the medicine (like a liquid) may be more appropriate. Check with your pharmacist or doctor if you are not sure.

Use in children below 3 months of age:

Children below 3 months of age should not take Nitrofurantoin.

Method of Administration
Nitrofurantoin should always be taken with food or milk. Taking this medicine with food or milk makes it work more effectively.
Capsules should be swallowed whole.
Do not forget to take your medicine.

Medical checks:
Your doctor will watch 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.

If you take more Nitrofurantoin 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 Nitrofurantoin:
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:
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 medicine, ask your doctor, pharmacist or nurse.

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 go to a doctor immediately.

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

- A group of blood disorders that affect the nervous system or skin, or both (Acute porphyria).
- Your lungs may react to Nitrofurantoin. This may develop quickly, within a week of starting treatment or very slowly, especially in elderly patients. This may produce fever, chills, cough, shortness of breath, collapse or a blue colouring to your skin. Scarring due to damaged lung tissue may occur.
- Jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes). Liver failure which may be fatal may also occur.
- The nerves outside the spinal cord may be affected causing changes to the sense of feeling and the use of muscles. Treatment should be stopped at the first signs of a

tingling sensation or numbness in the hands or feet. 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).
- 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 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 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)
- Damage to bone marrow causing deficiency of the red blood cells (Anaemia)

Not known (frequency cannot be estimated from the available data)
- 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
- Feeling sick
- Diarrhoea (Loose stools)
- Loss of appetite, stomach ache, and being sick
- A variety of skin rashes or reactions have occurred in some patients. Cases of a severe form of drug reaction with involvement of skin and other parts of the body (DRESS syndrome) are also reported. 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
- 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 (psychosis), 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 may slightly blur vision) may occur. These effects may be severe and in some instances permanent
- Fatigue, chills and drug fever
- Short-term hair loss
- Urinary infection 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
- Nitrofurantoin may interfere with the results of some tests for glucose in the urine.

Reporting 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. 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 and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nitrofurantoin contains

The active substance is nitrofurantoin.
Each hard capsule contains 50 mg or 100 mg nitrofurantoin.

The other ingredients are talc, maize starch and lactose monohydrate. The capsule shell contains gelatin, titanium dioxide (E 171) and iron oxide yellow (E 172).

What Nitrofurantoin looks like and contents of the pack:

Nitrofurantoin 50 mg have a yellow cap and ivory-yellow body and contain yellow or yellow-white powder.

Nitrofurantoin 100 mg have an ivory-yellow cap and body and contain yellow or yellow-white powder.

Nitrofurantoin are available in blisters containing 14, 15, 28, 30, 56, 60, 84 or 90 hard capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Activase Pharmaceuticals Limited
11 Boumpoulinas,
P.C. 1060, Nicosia
Cyprus

Manufacturer

Elara Pharmaservices Europe Limited
Regus Block 1, Blanchardstown Corporate Park,
Ballycoolin Road, Blanchardstown, Dublin 15,
D15 AKK1, Ireland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Ireland: Nitrofurantoin 50 mg hard capsules & Nitrofurantoin 100 mg hard capsules
Netherland: Nitrofurantoine Activase 50 mg harde capsules & Nitrofurantoine Activase 100

mg harde capsules
Belgium: Nitrofurantoin Activase 50 mg gélule & Nitrofurantoin Activase 100 mg gélule
Portugal: Nitrofurantoína 50 mg Cápsula & Nitrofurantoína 100 mg Cápsula
Slovenia: Nitrofurantoin Activase 50 mg kapsule & Nitrofurantoin Activase 100 mg kapsule

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