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 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 is and what it is used for
2. What you need to know before you take Nitrofurantoin
3. How to take Nitrofurantoin
4. Possible side effects
5. How to store Nitrofurantoin
6. Contents of the pack and other information

1. What Nitrofurantoin is and what it is used for

Nitrofurantoin (the active substance in Nitrofurantoin hard 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

Do not take Nitrofurantoin:
- If you are allergic to nitrofurantoin, other nitrofurans or to any of the other 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, pharmacist or nurse before taking Nitrofurantoin.
- 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. 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.
- 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 taken or might take any other medicines.

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 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.

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 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 contains sodium.
This medicine contains less than 1 mmol sodium (23 mg) per each hard 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.

The recommended dose is:
Adults:
The normal dosage depends on the type of infection you have and appropriate 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 50mg capsule or 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 three days thereafter.

Use in 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.
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 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.

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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 or the child has 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 have been told, even if you start to feel better.

If you have any further questions on the use of this medicine, 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, lips or tongue, 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.
- 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, involuntary eye movement (which may cause the eye to rapidly move from side to side, up and down or in a circle, and slightly blur 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 (cyanosis)
- Symptoms of fever, flu, abdominal pain, diarrhea, 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 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)

Not known (frequency cannot be estimated from the available data)
- Feeling sick (nausea) and headache
- Loose stools
- 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 (causing severe abdominal pain) and joint pains
- Short-term hair loss
- Urinary infection by germs or fungi 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

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 the national reporting system listed in the Yellow Card Scheme at: 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

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

This medicine does not require any special storage conditions.

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 substances is Nitrofurantoin.
  Each hard capsule contains 50 mg of Nitrofurantoin in macrocrystalline form.
  Each hard capsule contains 100 mg of Nitrofurantoin in macrocrystalline form.
- The other ingredients are:
  Capsules content: Cellulose Microcrystalline (Grade 101), croscarmellose Sodium, magnesium stearate
  Capsules shell: Iron oxide yellow (E172), titanium Dioxide (E171), gelatin
  Printing Ink: Shellac, black iron oxide (E172), Potassium hydroxide (E525)

What Nitrofurantoin looks like and contents of the pack
Hard Capsule.

Nitrofurantoin 50 mg hard capsules
Hard gelatin capsules of size '4' with white opaque body imprinted with '50' and yellow opaque cap imprinted with 'NMC' with black ink, filled with yellow to light yellow granular powder.

Nitrofurantoin 100 mg hard capsules
Hard gelatin capsules of size '2' with yellow opaque body imprinted with '100' and yellow opaque cap imprinted with 'NMC' with black ink, filled with yellow to light yellow granular powder.

Nitrofurantoin hard capsules are available in Clear PVC - Aluminium foil blister.
Pack sizes: 30 hard capsules

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This leaflet was last revised in 06/2023.

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