Nitrofurantoin is an antibiotic. It is used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract.

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What is Nitrofurantoin and what is it used for?
The name of this medicine is Nitrofurantoin which contains the active substance, nitrofurantoin BP and is available in strengths of 50 mg and 100 mg per tablet.

Nitrofurantoin is an antibiotic. It is used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract.

What you need to know before you take your medicine

Do not take these tablets 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 of this medicine (listed in section 6)
- 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 Nitrofurantoin if you:
- have any disease of the lungs, liver or nervous system. If you need to take Nitrofurantoin Tablets for a number of months, your doctor may want to regularly check how your lungs and liver are working
- 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)
- have diabetes
- are suffering from any illness causing severe weakness
- are on long-term therapy (especially elderly receiving the treatment)
- 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, like pins and needles.
- have false positive results on testing your urine for glucose
- your urine is dark yellow or brown coloured.
- 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)

Other medicines and Nitrofurantoin:
Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines, including medicines obtained without prescription.

You can take these tablets with other medicines, but there are some medicines that can interfere with Nitrofurantoin tablets:
- Antacids for indigestion (e.g. magnesium trisilicate)
- Medicines for gout (e.g. probenecid or sulfinpyrazone)
- Medicines for raised pressure in the eye (glaucoma), such as carbonic anhydrase inhibitors (e.g. acetazolamide)
- There is an increased absorption of Nitrofurantoin with food
- Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine)
- Medicines which make the urine less acidic (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.

Nitrofurantoin with food and drink

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

Important information about some of the ingredients in Nitrofurantoin:
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 your medicine Nitrofurantoin

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

Nitrofurantoin tablets are taken by mouth and only in the doses prescribed by your doctor. Do not take more of it and do not take it more often or for a longer time than your doctor ordered.

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. Below are examples of usual doses given.

**Adults and Elderly:**

Uncomplicated acute urinary tract infections:
- 50 mg (one 50 mg tablet) four times a day for seven days.

Severe chronic recurrence:
- 100 mg (one 100 mg tablet/two 50 mg tablets) four times a day for seven days.

Long-term suppression:
- 100 mg (one 100 mg tablet/two 50 mg tablets) once a day

Prophylaxis (prevention):
- 50 mg (one 50 mg tablet) four times a day for duration of any surgical procedure and continue for 3 days thereafter.

**Use in Children:**

Children (above 3 months of age):
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 Tablets.

**Medical Checks:**

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

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

If you accidentally take more tablets than recommended contact your nearest doctor or hospital casualty department at once. Take any remaining tablets with you and keep in the original container or packaging so that they can be identified.

**If you forget to take Nitrofurantoin**

If you miss a dose, skip the missed dose and go back to your regular dosage schedule.Do not take two doses at once.

**If you stop taking Nitrofurantoin**

You should not stop taking Nitrofurantoin Tablets suddenly. 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 feel that this medicine is not working as well after you have taken it for a short time (1 week) do not increase the dose, instead check with your doctor.

If you have any further questions on the use of this medicine, ask your doctor.

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 Tablets.

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 Tablets and consult your doctor.

- Respiratory: chest pain, changes in ECG, collapse and cyanosis, your lungs may react to nitrofurantoin Tablets. 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
- Hepatic: active hepatitis, jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes)
- Neurological: nystagmus, 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, blurred vision may occur. These effects may be severe and in some instances permanent

**Please note** that while taking Nitrofurantoin Tablets 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:**

- 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 infection by germs which are not sensitive to Nitrofurantoin Tablets.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**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: www.mhra.gov.uk/yellowcard. 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.

Keep your medicine in a dry place, below 25ºC in a well-closed container. Protect from light.

If your doctor tells you to stop the treatment, return any remaining tablets to the pharmacist. Only keep the medicine if the doctor tells you to.

On the label you will find the words “Expiry Date” followed by numbers indicating the day, month and year. This is the date when the medicine is no longer fit for use. Do not throw away any dispose of your medicines via waste water or household waste. Ask your pharmacist how to throw away dispose of medicines which you no longer require. These measures will help protect the environment.

6. **Content of the Pack and other information**

Nitrofurantoin tablets is available in strengths of 50 mg and 100 mg per tablet as follows:
Nitrofurantoin 50 mg tablets contain 50 mg nitrofurantoin BP.
Nitrofurantoin 100 mg tablets contain 100 mg nitrofurantoin BP.

Both strengths are flat, yellow bevelled and scored tablets and contain lactose, maize starch, pregelatinised maize starch, sodium starch glycollate, magnesium stearate.

Both strengths of Nitrofurantoin tablets are available in containers and blister packs of 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1,000 tablets.
Marketing Authorisation Holder
Chelonia Healthcare Limited, Boumpoulinas 11, 3rd Floor, Nicosia, P.C.1060, Cyprus

The Manufacturer
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This leaflet was last revised in September 2016.