

NITROFURANTOIN

50 mg & 100 mg TABLETS

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

1. WHAT NITROFURANTOIN TABLETS IS AND WHAT IT IS USED FOR

Nitrofurantoin is an antibiotic. It can be used to treat and prevent bacterial 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 TABLETS

Do not take Nitrofurantoin tablets and tell your doctor if:

- you are allergic to Nitrofurantoin or any of the other ingredients of this medicine (listed in section 6) or to other nitrofurantoin antibiotics. The signs of an allergic reaction include a rash, itching or shortness of breath
- you have problems with your kidneys (other than infection). Your doctor will assess whether you may take Nitrofurantoin depending on how well your kidneys are working.
- you have a blood problem known as porphyria where you may have too many red blood cells
- you have glucose-6-phosphate dehydrogenase (G6PD) deficiency. This is a genetic disorder where the red blood cells are broken down under stressful conditions or due to taking medicines
- you are breast-feeding an infant with G6PD deficiency
- you are in the final stages of pregnancy (labour or delivery) as there is a risk that it might affect the baby.

This medicine should **not** be given to infants under 3 months old.

Warnings and precautions

Talk to your doctor or pharmacist **before** you take this medicine 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 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, like pins and needles.

- 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)

- 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
- you have false positive results on testing your urine for glucose
- your urine is dark yellow or brown coloured.

Children

Do not give Nitrofurantoin tablets to infants under 3 months of age

Other medicines and Nitrofurantoin tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because Nitrofurantoin can affect the way some other medicines work. Also, some medicines can affect the way Nitrofurantoin works.

- Other medicines to treat bacterial infections such as Quinolone antibiotics (e.g. Norfloxacin)
- Medicines to make your urine less acidic such as potassium citrate mixture
- Antacids for indigestion or heartburn such as Magnesium Trisilicate
- Probenecid or Sulfinpyrazone to treat pain and swelling of the joints (gout)
- Medicines called Anticholinergics (e.g. Atropine, hyoscine) used for lots of different types of illness such as eye, kidney, breathing or bowel problems
- Carbonic Anhydrase Inhibitors (e.g. Acetazolamide) to treat increased eyeball pressure (glaucoma).
- Oral contraceptives. Nitrofurantoin can make birth control pills less effective. An additional form of contraception should be used.
- Typhoid vaccine, which is given for the prevention of typhoid

Nitrofurantoin Tablets with food and drink and alcohol

Nitrofurantoin should be taken at meal times with food or milk. This lowers the chance of getting an upset stomach and also helps the absorption.

Avoid alcohol whilst taking Nitrofurantoin.

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 drowsiness, dizziness. Do not drive or operate machinery if you are affected in this way until such symptoms go away.

Nitrofurantoin Tablets contains lactose.

This medicine contains lactose (a type of sugar). If you know you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE NITROFURANTOIN TABLETS

Always take Nitrofurantoin tablets exactly as your doctor or pharmacist has told you. Check with your doctor before taking this medicine.

Taking this medicine

- take this medicine by mouth with food or milk
- as this medicine is an antibiotic, always finish the prescribed course.

The recommended doses are given below. These may be changed by your doctor:

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:

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 over 3 months old:

The dose depends on the weight of the child and will be provided by your doctor. Follow your doctor's instructions exactly.

Children under 3 months old:

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 Tablets than you should

Contact your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Take the package or container with you so the doctor knows what you have taken. The symptoms of an overdose may include nausea, vomiting or an upset stomach.

If you forget to take Nitrofurantoin Tablets

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Nitrofurantoin Tablets

Keep taking this medicine until the course is finished, unless you get any of the side effects listed in section 4 below. Your doctor will tell you how long to take the treatment. Do not stop earlier than you should.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nitrofurantoin can cause side effects, although not everybody gets them.

Most of them are mild and disappear when you stop taking Nitrofurantoin tablets.

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 get any of the following side effects, STOP TAKING Nitrofurantoin and see your doctor as soon as possible:

- problems with your lungs, your lungs may react to Nitrofurantoin tablets. This may develop quickly, within a week of starting treatment or very slowly, especially in elderly patients, which may cause shortness of breath, chest pain, chills, cough, general illness or fever
- 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.
- severe headache. This may be due to an increase in pressure inside the head
- yellowing of the skin or whites of the eyes (jaundice) or inflammation of the liver (hepatitis).

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)
- being sick (vomiting)
- stomach pain
- diarrhoea
- loss of appetite
- drowsiness
- dizziness or a feeling of spinning
- headache
- weakness
- temporary hair loss
- changes in the colour of your urine
- infections of the genitals or urinary tract, caused by bacteria which are not sensitive to Nitrofurantoin.
- 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

Reporting 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 the Yellow Card Scheme at 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 TABLETS

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package or container and keep the container tightly closed.

Do not use these tablets after the expiry date, which is stated on the package or container. The expiry date refers to the last day of that month.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nitrofurantoin tablets contain

The active ingredient in Nitrofurantoin 50 mg and 100 mg tablets is nitrofurantoin. The other ingredients are lactose, maize starch, pregelatinised maize starch, sodium starch glycolate and magnesium stearate.

What Nitrofurantoin tablets look like and contents of the pack

Nitrofurantoin 50 mg tablets are round yellow tablets with the marking MP23 on one side and a break line engraved on the other.

Nitrofurantoin 100 mg tablets are round yellow tablets with the marking MP24 on one side and a break line engraved on the other.

The tablets come in blister packs and containers of 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Genethics Europe Limited,
41-43 Klimentos Tower, Nicosia 1061, Cyprus.

Manufacturer

Haupt Pharma Berlin GmbH,
Moosrosenstrasse 7, 12347 Berlin, Germany

For more information about this product, please contact the Marketing Authorisation Holder.

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