

PACKAGE LEAFLET

Package leaflet: Information for the patient

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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 they 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 they it is used for

Nitrofurantoin belongs to a class of medicines called nitrofurans. The active substance, nitrofurantoin, kills most of the bacteria that cause urinary tract infections.

Nitrofurantoin is used to treat acute (sudden) infections of the urinary tract. A urinary tract infection is an inflammation of the urinary tract. This infection may cause symptoms such as pain and burning when urinating, often urinating in small amounts, and pain in the lower abdomen.

Nitrofurantoin treats these symptoms. This medicine is also prescribed to help prevent infections (e.g. when a bladder catheter is inserted or for operations on the urinary tract).

Nitrofurantoin may sometimes be used for long-term treatment of persistent urinary tract infections that are not affected by other medicines.

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 or any of the other ingredients in this medicine (listed in section 6)
- if you have kidney disease that seriously affects the kidneys (ask your doctor if you are not sure)
- if you suffer from porphyria (reduced red pigmentation in the blood)
- if you have deficiency in an enzyme called G6PD (glucose-6-phosphate dehydrogenase), which can quickly damage your red blood cells
- in infants under the age of 3 months
- if you have ever had a lung or liver reaction or a peripheral neuropathy (tingling, numbness or

weakness in the limbs) when using 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.

Talk to your doctor if you experience fatigue, yellowing of the skin or eyes, itching, skin rashes, joint pain, abdominal discomfort, feeling sick (nausea), vomiting, loss of appetite, dark urine and pale or grey-coloured stools. These may be symptoms of liver disorder.

With long-term treatment, especially in elderly people, regular monitoring is required by the doctor in order to detect possible side effects as soon as possible.

In some individuals with dark skin colour and of Afro-Caribbean, Mediterranean, Middle Eastern or Western Asian origin anaemia could develop during treatment. If you belong to this group and experience fatigue (feeling tired), dizziness and shortness of breath during treatment, stop taking this medicine and contact your doctor.

If you experience a tingling sensation or numbness in your hands or feet during treatment or a weak feeling in your limbs, stop taking this medicine and contact your doctor. The chance of these side effects increases when, for example, your kidneys are not working well. If you have diabetes or anaemia, or a disease that causes severe weakness, or you have had allergic reactions before, tell your doctor.

Complications in the lungs or liver may occur: see 'Possible side effects'. If such complications arise, the use of Nitrofurantoin must be stopped immediately.

Other medicines and Nitrofurantoin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some of these medicines may change the effect of Nitrofurantoin.

- Antacids for indigestion (e.g. magnesium trisilicate).
- Medicines for gout (e.g. probenecid or sulfinpyrazone).
- Medicines that 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 that 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 can influence the results of a number of tests for the determination of glucose in the urine.

Nitrofurantoin with food and drink

Nitrofurantoin should always be taken with food or milk. Taking this medicine with food or milk makes it work more effectively and will help to prevent stomach complaints.

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 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 harm the baby.

If you want to breast-feed, please ask your doctor before taking this medicine.

Driving and using machines

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

Nitrofurantoin 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 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.

Nitrofurantoin capsules are taken by mouth: swallow them during meals or with some milk or yogurt. This way this medicine is better tolerated and leads to the best results.

The recommended dose is:

Acute uncomplicated lower urinary tract infections:

For adults and children over 12 years, a dose of 1 capsule of 50 mg, 4 times per day (1 capsule with each meal and 1 before bedtime). General use for 5 to 7 days or at least 3 days after no infection is detectable in the urine.

In girls aged 5 to 12 years: 3 to 6 mg/kg body weight per day divided over 4 doses per day, also for 7 days or at least 3 days after no infection is detectable in the urine. This pharmaceutical form (capsules) may not be suitable for use in children in this age group.

Short-term prophylaxis for urinary tract surgery and inserting bladder catheters (adults and children over 12 years):

4 x 50 mg per day on the day of the procedure and for 3 days after.

Long-term treatment of urinary tract infections (adults and children over 12 years):

1 capsule of 50 or 100 mg per day usually in the evening before bedtime and after you last pass urine: for a maximum of 6 months.

When treatment is started, the symptoms can quickly decrease, usually within 1-3 days. Finally they usually disappear completely. Nevertheless, you should always completely finish the full course of treatment. The symptoms may have disappeared, but that does not mean that all the bacteria have already been killed. If you stop too early, the symptoms can return quickly, which is uncomfortable for you and medically undesirable. If after 3 days the discomfort is not gone, or is not greatly reduced, then visit your doctor again.

If you take more Nitrofurantoin than you should

Ask 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 have taken.

If you forget to take Nitrofurantoin

Do not worry. If you remember later 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 dose. 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. Speak to your doctor, pharmacist or nurse, if you are thinking about stopping treatment early.

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.

All medicines can cause allergic reactions, although serious allergic reactions are rare. If you have sudden shortness of breath, difficulty breathing, swelling of the eyelids, face or lips, skin rash or itching (especially affecting your whole body), **stop taking this medicine and go to a doctor immediately.**

If you experience any of the side effects listed below, stop taking Nitrofurantoin and see your doctor.

Nitrofurantoin can occasionally discolour the urine from dark yellow to brown. This is normal and disappears after the treatment.

If you notice any of the following side effects, tell your doctor immediately:

- 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 tissue damage.
- Nitrofurantoin can cause liver inflammation, resulting in jaundice (yellow discoloration of the skin or of the white of the eyes).
- in some patients the blood cells are affected, leading to bruises, delayed blood clotting, sore throat, fever, anaemia and susceptibility to colds or persistent common cold
- increased pressure in the skull (which causes severe headaches)
- severe allergic skin reactions (DRESS syndrome)
- various skin reactions, including skin peeling (flakes), redness skin rash or fever accompanied by a rapid heartbeat and severe blistering

Very common (may affect more than 1 in 10 people):

- urinary tract infection by bacteria that are not susceptible to nitrofurantoin
- short-term hair loss

Rare (may affect up to 1 in 1,000 people):

- loss of appetite
- feeling sick (nausea)
- loss of consciousness (collapse)
- bluish or grayish colour of the skin, nails, lips or around the eyes (cyanosis)

Not known (frequency cannot be estimated from the available data):

- headaches
- diarrhoea
- stomach pain, being sick (vomiting)
- dizziness, drowsiness

- The nerves can be affected, resulting in changes in sensitivity and the use of the muscles. In addition, headaches, extreme changes in mood or mental condition, confusion, weakness, poor vision.
- a feeling or state of intense excitement and happiness (euphoria)
- other reactions may include: inflammation of the salivary glands (causing pain in the face), inflammation of the pancreas (causing severe abdominal pain), joint pain
- inflammation in the blood vessels of the skin
- liver inflammation due to abnormal antibodies against liver cells (autoimmune hepatitis)
- inflammation of small blood vessel walls, causing skin lesions
- liver inflammation due to the immune system turning against liver cells
- inflammation of kidney tissue surrounding tubules, causing kidney problems

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 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.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Nitrofurantoin contains

The active substance is nitrofurantoin. Nitrofurantoin capsules are available in two strengths, containing either 50 mg or 100 mg of nitrofurantoin.

The other ingredients:

Capsule content; maize starch, lactose monohydrate (see section 2 'Nitrofurantoin contains lactose'), talc.

Capsule shell; titanium dioxide (E171), gelatin, yellow iron oxide (E172).

What Nitrofurantoin looks like and contents of the pack

Nitrofurantoin 50 mg hard capsule is a hard gelatin capsule with a yellow cap and white body.

Nitrofurantoin 100 mg hard capsule is a hard gelatin capsule with a yellow cap and yellow body.

Nitrofurantoin is available in blister packs containing 20 or 30 capsules and a bottle pack of 500 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan

Potters Bar

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Manufacturer(s)

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