

PACKAGE LEAFLET

Package leaflet: Information for the patient

Nitrofurantoin Kora Healthcare 50 mg and 100 mg 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 Kora Healthcare is and what it is used for
2. What you need to know before you take Nitrofurantoin Kora Healthcare
3. How to take Nitrofurantoin Kora Healthcare
4. Possible side effects
5. How to store Nitrofurantoin Kora Healthcare
6. Contents of the pack and other information

1. What Nitrofurantoin Kora Healthcare is and what it is used for

Nitrofurantoin Kora Healthcare contains the active substance nitrofurantoin. Nitrofurantoin belongs to a class of medicines called nitrofurans. Nitrofurantoin is an antibiotic, used to treat infections caused by bacteria.

Nitrofurantoin Kora Healthcare is used to treat acute (sudden) infections of the urinary tract. An inflammation of the urinary tract may cause symptoms such as pain and burning when urinating, often urinating in small amounts, and pain in the lower abdomen. Nitrofurantoin Kora Healthcare treats these symptoms.

Nitrofurantoin Kora Healthcare is also used to help prevent infections (e.g. when a bladder catheter is inserted or for operations on the urinary tract).

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

Nitrofurantoin Kora Healthcare is used in adults and children aged over 5 years.

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 Kora

Healthcare

Do not take Nitrofurantoin Kora Healthcare

- 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 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 (body chemical) called G6PD (glucose-6-

- phosphate dehydrogenase), which can quickly damage your red blood cells
- if you are in the final stages of pregnancy (labour or delivery) or breast-feeding an infant younger than one month of age, as there is a risk that it might affect the baby
 - if your child is under three months of age
 - if you have previously had a lung or liver reaction other than a peripheral neuropathy after use of 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 Kora Healthcare.

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.

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

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. Talk to your doctor if you have diabetes, anaemia, problems with alcohol, any electrolyte disorder or a disease that causes severe weakness, or if you have had allergic reactions before.

Talk to your doctor if you have any neurological disorders or allergic diathesis.

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

Medical Checks

Your doctor will watch carefully for any effects on the liver, lungs, blood or nervous system.

Other medicines and Nitrofurantoin Kora Healthcare

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 Kora Healthcare.

- 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 when taken by mouth.

If you are in doubt about any of these medicines, ask your doctor or pharmacist.

Nitrofurantoin Kora Healthcare can influence the results of a number of tests for the

determination of glucose in the urine.

Nitrofurantoin Kora Healthcare with food and drink

Nitrofurantoin Kora Healthcare should always be taken with food or milk. Taking this medicine with food or milk makes it work more effectively and 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 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.

You should avoid breast feeding an infant younger than one month, or an infant known or suspected to have any erythrocyte enzyme deficiency (including G6PD deficiency). If you want to breast-feed, please ask your doctor before taking this medicine.

Driving and using machines

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

Nitrofurantoin Kora Healthcare contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Nitrofurantoin Kora Healthcare

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 Kora Healthcare capsules are taken by mouth: swallow them during meals or with some milk. 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 one capsule of 50 mg four times per day (one capsule with each meal and one before bedtime). General use for five to seven days or at least three days after no infection is detectable in the urine.

In girls aged 5 to 12 years the usual dose is 3 mg/kg body weight up to a maximum of 6 mg/kg body weight per day divided over four doses per day for seven days or at least three days after no infection is detectable in the urine.

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

Short-term prophylaxis for urinary tract surgery and inserting bladder catheters

(adults and children over 12 years):

One capsule of 50 mg four times per day on the day of the procedure and for three days after.

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

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

When treatment is started, the symptoms can quickly decrease, usually within one to three 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 three days the discomfort is not gone, or is not greatly reduced, then visit your doctor again.

If you take more Nitrofurantoin Kora Healthcare 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 have taken.

If you forget to take Nitrofurantoin Kora Healthcare

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 Kora Healthcare

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.

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 Kora Healthcare 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 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

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

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
- high pressure around the brain

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)
- G6PD deficiency
- anaemia
- dermatitis, erythema, Stevens-Johnson syndrome
- cholestatic icterus and chronic hepatitis

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

- headaches
- diarrhoea
- stomach pain, being sick (vomiting)
- dizziness, drowsiness
- nystagmus
- The nerves can be affected, resulting in changes in sensitivity and the use of the muscles.
- allergic reactions (angioedema, anaphylactic reactions)
- 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
- 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 HPRC 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 Kora Healthcare

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 Kora Healthcare contains

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

The other ingredients are: maize starch, lactose monohydrate, talc.

50 mg capsules:

body: titanium dioxide (E171), gelatin

cap: yellow iron oxide (E172), titanium dioxide (E171), gelatin.

100 mg capsules:

body & cap: titanium dioxide (E171), yellow iron oxide (E172).

What Nitrofurantoin Kora Healthcare looks like and contents of the pack

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

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

Nitrofurantoin Kora Healthcare is available in blister packs containing 20 or 30 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Kora Corporation Ltd t/a Kora Healthcare

20 Harcourt Street

Dublin 2

D02 H364

Ireland

Manufacturers

- IASIS PHARMACEUTICALS HELLAS ABEE, 137, Filis Ave, Kamatero, Attiki, 13451, Greece.
- IASIS PHARMACEUTICALS HELLAS S.A. – KOROPHI, Archimidous Street, Koropi Attikis, 19 400 Greece

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

Cyprus	Furolin 50mg Capsule, hard
	Furolin 100mg Capsule, hard
Belgium	Nitrofurantoin Iasis Pharma 50 mg gélules
	Nitrofurantoin Iasis Pharma 100 mg gélules
Bulgaria	Furolin 100mg Капсула, твърда
Ireland	Nitrofurantoin Kora Healthcare 50mg Capsule, hard
	Nitrofurantoin Kora Healthcare 100mg Capsule, hard
Malta	Furolin 50mg Capsule, hard
	Furolin 100mg Capsule, hard
Romania	Furolin 50mg Capsulă
	Furolin 100mg Capsulă
Slovak Republic	Nitrofurantoin Pharmedid 100mg tvrdé kapsuly

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