

Patient package insert according to Pharmacists' Regulations (Preparations) -1986

This medicine can be sold with a physician's prescription only

NITROFURANTOIN RAZ 100MG Hard capsules

Active ingredient:

Each capsule contains 100mg Nitrofurantoin (as macrocrystals).

For a list of inactive and allergenic substances in the medicine – see section 6 “additional information” and in section 2 “Important information about some of the ingredients of this medicine”.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any additional questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine intended for?

Nitrofurantoin Raz 100mg is indicated for the treatment of and prophylaxis against acute or recurrent, uncomplicated lower urinary tract infections when due to susceptible microorganisms **in adults and adolescents 12 years and older.**

Pharmacotherapeutic group: Antibacterials for systemic use from nitrofurantoin derivatives.

2. Before using the medicine:

Do not use the medicine if:

- | |
|---|
| <ul style="list-style-type: none">- You are sensitive (allergic) to the active substance nitrofurantoin, nitrofurans or any of the other ingredients of this medicine (see section 6, "additional information").- You have a disease of the kidneys, which is severely affecting the way that they work (eGFR < 45 ml/min);- You are in the final stages of pregnancy (labour or delivery), as there is a risk that this medicine might affect the baby.- You suffer from a blood disorder called porphyria.- You are deficient in an enzyme called G6PD (glucose-6-phosphate dehydrogenase) or you are breast feeding a baby who has a suspected or a known G6PD enzyme deficiency.- Your infant is under three months of age (See details in the 'Children and Adolescents' section). |
|---|

Special warnings regarding the use of this medicine:

Talk to your doctor or pharmacist before taking Nitrofurantoin Raz 100mg (and during treatment) if:

- You have diabetes.
- You are suffering from any illness which is causing severe weakness.
- You have anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness), 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.
- You have any problems with your kidneys. See also 'Do not use the medicine if'.

The above conditions may increase the chance of developing side effects which result in damage to the nerves, causing an altered sense of feeling or sense of pricking, tingling or numbness on the skin.

- You lack an enzyme called glucose-6-phosphate dehydrogenase (G6PD), condition which causes your red blood cells to be more easily damaged (this is more common in people of dark skin, or Mediterranean, Middle Eastern or Asian origin). See also 'Do not use the medicine if'.
- You have disease of the lungs.
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, pain or discomfort when breathing. These may be symptoms of side effects affecting the lungs (please see also section 4).
- You have any disease of the liver or nervous system. If you need to take **Nitrofurantoin Raz 100mg** for a number of months, your doctor may want to regularly check how your lungs and liver are working.
- 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 grey-coloured stools. It may be symptoms of liver disorder (please see also section 4).

Additional warnings:

This medicine may cause your urine to turn yellow or brown.

Interference with urine tests:

This medicine interferes 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.

Medical Checks:

Your doctor will monitor you carefully for any effects of the medicine on the liver, lungs, blood or nervous system.

Nitrofurantoin Raz 100mg may interfere with the results of some tests for glucose in the urine.

Children and adolescents

Nitrofurantoin Raz 100mg is intended for children 12 years and older.

Do not use in infants under three months of age. See also 'Do not use the medicine if'.

Infants 3 months to children 12 years of age:

Nitrofurantoin Raz 100mg is not indicated for infants between 3 months to children 12 years of age since it is forbidden to chew or crush the capsule, and the content of the capsule should not be opened or dispersed to adjust the dose per weight in this age group.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist because their effect or the effect of nitrofurantoin may vary. In particular if you are taking:

- Antacids for indigestion (e.g. magnesium trisilicate) - decrease the absorption of nitrofurantoin.
- Medicines for gout (e.g. probenecid or sulfinpyrazone) – decrease the renal excretion of nitrofurantoin.
- Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine) - increase the absorption of nitrofurantoin.
- Medicines for increased pressure in the eye (glaucoma), such as carbonic anhydrase inhibitors (e.g. acetazolamide) – decrease the anti-bacterial activity of nitrofurantoin.
- Medicines which make the urine less acidic (e.g. potassium citrate mixture) – decrease the anti-bacterial activity of nitrofurantoin.
- Medicines known as quinolones (used to treat infections) – antagonise the anti-bacterial activity of nitrofurantoin.
- Typhoid vaccine (oral), which is given for the prevention of typhoid - nitrofurantoin inactivates the typhoid vaccine when taken orally.
- Oestrogens: similar with other antibiotics, nitrofurantoin may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of oestrogen-containing contraceptive products. Therefore, patients should be warned appropriately, and extra contraceptive precautions taken.

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

Use of this medicine and food:

Nitrofurantoin Raz 100mg should always be taken with food or milk. Taking this medicine with food or milk makes it work more effectively, this will help to avoid stomach upset and also aid absorption.

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your doctor or pharmacist before taking this medicine.

As far as it is known, **Nitrofurantoin Raz 100mg** may be used in pregnancy in some months of pregnancy.

However, **Nitrofurantoin Raz 100mg** should not be used during the final stages of pregnancy (labour or delivery) because there is a possibility that taking this medicine at this stage may affect the baby.

If you want to breast-feed, please consult your doctor first.

Do not use the medicine if you are breast feeding a baby who has a suspected or a known G6PD (glucose-6-phosphate dehydrogenase) enzyme deficiency.

There is no information on the effect of nitrofurantoin on fertility.

Driving and using machines:

Nitrofurantoin Raz 100mg may cause dizziness and drowsiness. You should not drive or operate machinery if you are affected in this way.

Important information about some of the ingredients of this medicine:

Nitrofurantoin Raz 100mg contains lactose monohydrate (see section 6, “additional information”).

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 use this medicine?

Always use this medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

The usual dosage is:

Adults and adolescents 12 years and older:

For the treatment of infections:

100 mg, 3-4 times a day.

Treatment should be continued, as a rule, for 1 week, or at least 3 days after obtaining sterile urine.

Administration in prophylaxis and suppression:

When treatment is justified, a daily dose of 100 mg at bedtime is suggested for adults and adolescents 12 years and older.

This medicine is not suitable for use in children under 12 years of age.

Do not exceed the recommended dose.

Method of administration

Swallow the capsules whole, always with food or milk (the capsules should not be crushed or chewed).

In the absence of suitable data, it is forbidden to open and disperse the content of the capsule.

If you have accidentally taken a higher dosage:

If you have taken an overdose or if a child has accidentally swallowed the medicine, contact a doctor or a hospital emergency room immediately and bring the medicine package with you.

Symptoms and signs of overdose include gastric irritation, nausea and vomiting.

If you forget to take the medicine:

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose.

If you stop taking the medicine:

The treatment should be continued as recommended by the doctor.

Even if there is an improvement in your health condition, you should not stop taking the medicine without consulting your doctor.

Your doctor will tell you how long to take this medicine. Do not stop sooner than you have been told, even if you feel better.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

Like any medicine, the use of nitrofurantoin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

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

All medicines can cause allergic reactions, although serious allergic reactions are rare. If you notice any sudden wheeziness when breathing, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body), **stop taking the medicine and see a doctor immediately.**

If you notice any of the following side effects consult 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/or tissue damage. See also 'Special warnings regarding the use of this medicine' section.

If you experience any of the side effects detailed below stop taking

Nitrofurantoin Raz 100mg and consult your doctor:

- 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 lightly 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 colouration of the skin due to low oxygen levels (a condition known as cyanosis).
- Symptoms of fever, flu, abdominal pain, diarrhoea, 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 Raz 100mg** 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 side effects (effects that appear in up to 1 in 1,000 people):

- Loss of consciousness (collapse).
- Damage to bone marrow causing deficiency of the red blood cells (anaemia).

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- Feeling nausea and headache.
- Diarrhea.
- Loss of appetite, stomach ache and vomiting.
- Dizziness, drowsiness.
- Affect on blood cells. This may result in bruising, delayed clotting of the blood, sore throat, fever, anaemia, and a susceptibility to colds or a persistent cold.
- A variety of skin rashes or reactions. 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 caused by germs which are not sensitive to nitrofurantoin.
- 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 the tubules, causing renal impairment.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking the link “report side effects due to medication” that can be found on the homepage of the Ministry of Health website (www.health.gov.il) directing to an online form for reporting side effects, or by clicking the link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

- **Avoid poisoning!** This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. Date) stated on the package. The expiry date refers to the last day of that month.

- **Storage conditions:** This medicinal product does not require any special storage conditions, but it is recommended to be stored in room temperature.

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

6. Additional information

In addition to the active ingredient, this medicine also contains:

lactose monohydrate, pregelatinised starch, talc.

Each capsule of **Nitrofurantoin Raz 100mg** contains 180.80 mg of Lactose monohydrate.

The capsule shell and body contains:

Purified water, Titanium dioxide (E171), Quinoline yellow (E104), Iron oxide yellow (E172), Gelatin.

The black printing ink contains:

Shellac, Propylene glycol, Potassium hydroxide and Black iron oxide.

What does the medicine look like and what does the package contain:

Nitrofurantoin Raz 100mg is yellow hard gelatin capsule containing yellow powder, “EM29” printed in black and thin black band around.

The capsules are packed in white PVC\aluminum blisters.

Nitrofurantoin Raz 100mg is available in the following packages:

Pack of 20 capsules (2 blisters with 10 capsules each)

or

Pack of 30 capsules (3 blisters with 10 capsules each)

Not all pack sizes may be marketed.

Marketing authorization holder and importer:

Raz Pharmaceuticals LTD, 31 Geshet Haetz St., Industrial park, Emeq hefer, 3877701, Israel

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 175-65-37315-99.

This leaflet was approved in June 2024.

RAZP0525-U-00

Nitrofurantoin Raz 100mg PIL PB0125-03