PACKAGE LEAFLET: Information for the user

NITROFURANTOINE

Tablets – 100 mg

(Nitrofurantoin)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT NITROFURANTOINE IS AND WHAT IT IS USED FOR

Nitrofurantoin is an antibacterial, which belongs to the group of nitrofuranes.

The mechanism of action of nitrofurantoin has not yet been clarified. There is evidence that this substance inhibits a range of enzymatic systems of bacteria and confirmed that it interferes in the early stages of bacterial carbohydrate metabolism, by inhibiting acetyl coenzime A.

Nitrofurantoin acts against a broad spectrum of common pathogen microbes of urinary tract.

Most strains of *Escherichia coli* are sensitive; also, most of strains of *Klebsiella - Enterobacter* are sensitive to nitrofurantoin.

Nitrofurantoine is indicated in prophylaxis and treatment of acute or recurrent, uncomplicated lower urinary tract infections, either spontaneous or following surgical procedures.
Nitrofurantoine is specifically indicated for the treatment of infections when due to susceptible strains of *Escherichia coli*, *Enterococci*, *Staphylococci*, *Citrobacter, Klebsiella* and *Enterobacter*. Most strains of *Proteus* and *Serratia* are resistant. All *Pseudomonas* strains are resistant.
Your doctor may have given you Nitrofurantoine for another reason. Ask your doctor if you want to know why you were given Nitrofurantoine.

2. BEFORE YOU TAKE NITROFURANTOINE

Do not take Nitrofurantoine if you:

- are hypersensitive to nitrofurantoin, other nitrofuranes or to any of the excipients of this product;
- have renal function impairment with creatinine clearance lower than 60 mL / min. or high level of creatinine in serum;
- have acute porphyria;
- have deficiency of glucose-6-phosphate dehydrogenase.

Nitrofurantoine is contraindicated in infants under three months of age as well as pregnant patients (at term or during labour and delivery) because of the theoretical possibility of haemolytic anaemia in the foetus or in the newborn infant due to immature erythrocyte enzyme systems.
Nitrofurantoine is not indicated for the treatment of combined renal cortical or peripheric abscesses.

Take special care with Nitrofurantoine

Tell your doctor if you:

- have gastrointestinal effects (they can be minimized by taking the drug with food or milk, or by adjusting the dose);
- have lung disease (in long-term therapy monitor for pulmonary symptoms, especially in the elderly – discontinue if deterioration in the lung function);
- have liver function impairment (in long-term therapy monitor liver function);

- have neurological disorders;
- have allergic diathesis;
- suffer from diabetes;
- suffer from anaemia;
- have electrolyte imbalance and vitamin B defficiency (especially folic acid);
- are predisposed to peripheral neuropathy;
- 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 gray-colored stools. These may be symptoms of liver disorder.

Nitrofurantoine may cause hemolysis in patients with glucose-6-phosphate dehydrogenase deficiency.

During long-term treatment, the patient should be carefully monitored for the possible hepatic, pulmonary or neurological symptoms (especially the elderly).

Nitrofurantoine may cause false positive reactions in urine tests for glucose.

Urine may be coloured yellow or brown because of nitrofurantoin.

Taking other medicines

Concomitant treatment with other drugs, may affect or be affected by Nitrofurantoine.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those without a prescription. Remember to inform your doctor if you are given another drug during treatment, especially the ones below:

- anticholinergic drugs and food increase the absorption of nitrofurantoin;
- magnesium salts may decrease the absorption of this substance;
- probenecid and sulfinpyrazone may increase the levels of nitrofurantoin in serum, by decreasing its urinary elimination;
- nitrofurantoin may antagonise the effects of nalidixic acid and quinolones;
- drugs which are known for their hepatotoxic, hemolytic or neurotoxic effects; these drugs should not be taken concomitantly with Nitrofurantoine.

Taking Nitrofurantoine with food and drinks

Nitrofurantoine tablets may be taken with food and milk to minimize the gastrointestinal effects

and to help its absorption.

Pregnancy

Tell your doctor if you are pregnant or plan to become pregnant during treatment.
It is contraindicated in pregnancy at term or during labour and delivery because of the theoretical possibility of haemolytic anaemia in the foetus or in the newborn infant due to immature erythrocyte enzyme systems.

Breastfeeding

Tell your doctor if you are breastfeeding.
Nitrofurantoin should be avoided during breastfeeding.

Driving and using machines

Nitrofurantoine may cause dizziness and drowsiness. If you notice any of these side effects, then do not drive or use machines.

3. HOW TO TAKE NITROFURANTOINE

Always take Nitrofurantoine as your doctor has told you. If you are not sure, contact with your doctor or pharmacist. If you feel that the effect of Nitrofurantoine is too strong or too weak, talk to your doctor or pharmacist. The tablets should be swallowed with at least half glass of water.

In uncomplicated acute infections of the urinary tract: 50 mg, 4 times a day, for 7 days.
In severe chronic recurrent infections: 100 mg, 4 times a day for 7 days. In cases of severe nausea, the dose can be reduced, but not less than 200 mg per day. If the nausea continues, the treatment should be stopped.
In surgical prophylaxis: 50 mg, 4 times a day, before the procedure and 3 days after.
Children over 3 months: *In acute urinary tract infections*: 3 mg / kg body weight per day in 4 divided doses, for 7 days.
Your doctor may decide for you to take Nitrofurantoine for a longer time. Ask your doctor for advice if you are not sure for how long you should take the tablets.

If you take more Nitrofurantoine than you should

If you take more Nitrofurantoine than you should, or if the children have taken this medicine by accident, please contact your doctor, the hospital or call the emergency to get an opinion of the risk and advice on the actions to be taken.

If you forget to take Nitrofurantoine

If you forget a dose, take the next dose when it is the normal time to take it.

Do not take a double dose to make up for the forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

All medicines can cause side effects. Sometimes they may be serious, sometimes not. Do not panic from this list of possible side effects. You may not get any of them. Inform your doctor if any of the following side effects bothers you. Long term use and high doses may favor these effects:

- gastrointestinal reactions: anorexia, nausea, vomiting, and diarrhea;
- dizziness and drowsiness;
- acute and chronic pulmonary reactions;
- peripheral neuropathy;
- hypersensitivity reactions are reported (angioedema, urticaria, rash and pruritus); inflammation of small blood vessel walls, causing skin lesions with a frequency not known;
- rarely, cholestatic jaundice, hepatitis, liver inflammation due to turn of immune system against liver cells with a frequency not known, exfoliative dermatitis, erythema multiforme, pancreatitis, arthralgia, blood disorders (including agranulocytosis, thrombocytopenia, and aplastic anaemia), inflammation of kidney tissue surrounding tubules, causing renal impairment with a frequency not known, benign intracranial hypertension and transient alopecia.

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE NITROFURANTOINE

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the package.

Do not store above 25°C.

Store in the original packaging to protect the tablets from light and humidity.

6. FURTHER INFORMATION

What Nitrofurantoine contains

The active substance is nitrofurantoin.

Each tablet contains 100 mg nitrofurantoin.

The excipients are: maize starch, talc, magnesium stearate, povidone.

Contents of the pack

Box with 20 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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