



P37931



# Nitrofurantoin/ IASIS

## Nitrofurantoin

**Package leaflet: information for the user**  
**Nitrofurantoin/IASIS 25mg/5ml oral suspension**  
Nitrofurantoin

**Read carefully the whole package leaflet before you start taking this medicine, as it contains important information for you.**

- Keep this package leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed only for you. Do not pass the medicine on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, tell your doctor or pharmacist. This also applies to any possible side effects not listed in this package leaflet. See section 4.

### **What is contained in this package leaflet:**

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

### **1. What Nitrofurantoin/IASIS is and what it is used for**

Nitrofurantoin (the active substance in Nitrofurantoin/IASIS) is an antibiotic. It is used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract

### **2. What you need to know before you take Nitrofurantoin/IASIS**

#### **Do not use Nitrofurantoin/IASIS:**

- if you are allergic to Nitrofurantoin, to other medicines containing nitrofurantoin or to any other ingredient of this medicine (listed in Section 6)
  - if you have a disease of the kidneys, which is severely affecting the way they function (check with your doctor if you have any doubts)
  - if you are in the final stages of pregnancy (labour or delivery), as there is a risk that it might affect the baby
  - if you suffer from a blood disorder called porphyria
  - if you are deficient in an enzyme called G6PD (glucose-6-phosphate dehydrogenase)
  - if your child is under three months of age.
- Tell your doctor if you have any doubts about any of the above.

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Nitrofurantoin/IASIS, 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
- you have problems with your kidneys.

The above situations may increase the possibility of developing a side effect, which results in damage to the nerves, causing disruption of sensation and pain like pinch of a pin or 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/IASIS for several months, your doctor may want to regularly check the function of your lungs and liver.

This medicine may interfere with urine tests for glucose, causing the test to give a "false positive" result. That is, the test may indicate that there is glucose in the urine even if this is not the case. This medicine may also cause your urine to turn yellow or brown.

Talk to your doctor, if 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 gray-colored stools. They may be symptoms of liver disorder.

#### **Other medicines and Nitrofurantoin/IASIS**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including non-prescription medicines.

If they are taken along with Nitrofurantoin/IASIS, their effect or the effect of Nitrofurantoin/IASIS may be changed.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Antacids for indigestion (e.g. magnesium trisilicate)
- Typhoid vaccine
- 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.

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

#### **Nitrofurantoin/IASIS with food and drink**

Nitrofurantoin/IASIS should be taken at mealtimes along with food or milk. This will help to avoid stomach upset and also to help the absorption of the medicine.

#### **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/IASIS may be used in pregnancy. However, it should not be used during labour or delivery itself, as there is a possibility that the use at this stage may affect the baby. If you want to breast feed, please consult your doctor first.

#### **Driving and using machines**

Nitrofurantoin/IASIS may cause sleepiness and dizziness. You should not drive or operate machinery if you are affected in this way until such symptoms go away.

#### **Nitrofurantoin/IASIS contains**

- Methylhydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed) and exceptionally, bronchospasm
- Glycerol which can cause headache, stomach upset and diarrhoea
- Less than 1mmol sodium per dose, i.e. it is actually sodium free.

### **3. How to take Nitrofurantoin/IASIS**

Always take this medicine strictly in accordance with your doctor's or pharmacist's instructions. Check with your doctor or pharmacist if you have any doubts.

#### **Adults**

The normal dosage depends on the type of infection you have and the 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:

- For treatment of infections: two to four 5ml doses four times a day for seven days
- For prevention of further infections: two to four 5ml doses to be taken once a day
- For prevention of infections during surgery: two 5ml doses four times a day on the day of the operation and three days thereafter.

#### **Use for children and infants aged over three months**

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

**Children under 3 months of age should not take Nitrofurantoin/IASIS.**

#### **Medical Checks:**

Your doctor will watch carefully for any effects on the liver, lungs, blood or nervous system. Nitrofurantoin/IASIS may interfere with the results of some tests for glucose in the urine.

#### **Method of administration**

This medicine should be taken during mealtime, along with food or milk.

It is recommended to shake well before use, until complete resuspension.



Please use the plastic spoon or the plastic dosing syringe (see instructions below) provided to deliver the specific dose.

#### How to use the plastic dosing syringe

The syringe can be used to measure your dose by drawing the liquid up to the correct mark on the syringe.

1. Shake the bottle well, after making sure the cap is firmly placed on the bottle.
2. Remove the cap. Note: Keep the cap nearby, so that you close the bottle after each use.
3. Push the plastic adapter into the neck of the bottle. Note: The adapter must always stay inside the bottle.
4. Take the syringe and check the plunger is fully down.
5. Keep the bottle upright and insert the oral syringe firmly into the plastic adapter
6. Turn the whole bottle with the syringe upside down.
7. Pull slowly the plunger down, so that the syringe fills with medicine. Push the plunger fully upwards to expel any large air bubbles that may be trapped inside the oral syringe.
8. Then pull the plunger slowly back to the mark of volume you need for your dose.
9. Turn the whole bottle with the syringe upright and take the syringe out of the bottle.
10. The dose of medicine can now be swallowed directly from the oral syringe. Please ensure that you are sitting upright and you are pushing the plunger slowly, so that you can swallow the dose.
11. Replace the child resistant cap after use, leaving the adapter in place.
12. Cleaning: After use, wipe the outer part of the syringe with a dry, clean tissue

#### If you take a bigger dose of Nitrofurantoin/IASIS than you should

Consult your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any left-over medicine 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/IASIS

Do not worry. If you remember it later on 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 the forgotten dose. If you have any doubts, ask your doctor or pharmacist.

#### If you stop taking Nitrofurantoin/IASIS

Your doctor will advise you for how long you will take the treatment. Do not stop earlier than you are told, even if you feel better.

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

#### 4. Possible side effects

Like all medicines, this medicine can also cause side effects, although they do not appear to everybody. Most of them are mild and disappear when you stop taking Nitrofurantoin/IASIS.

All medicines can cause allergic reactions, although serious allergic reactions are rare. If you experience 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 experience any of the side effects detailed below, consult your doctor immediately:

- Your lungs may react to Nitrofurantoin/IASIS. This side effect may develop quickly, within a week from starting treatment or very slowly, especially in elderly patients. This may produce fever, chills, cough and shortness of breath.
- Jaundice (inflammation of the liver causing yellowing of the skin or of the whites of the eyes).
- The nerves outside the spinal cord may be affected, causing disruption of sensation and of the use of muscles. In addition, headache, extreme changes of mood or mental state (psychosis), confusion, weakness, blurred vision may occur. These effects may be severe and, in some cases, permanent.
- Raised pressure in the skull (causing severe headaches)
- Severe reduction of blood cells, which can cause weakness, bruising or make infections more likely.
- Blue or purple coloration of the skin due to low oxygen levels. A condition known as cyanosis.
- Symptoms of fever, flu, abdominal pain, diarrhea, blood in your stool and weakness. These could be signs of a condition known as cutaneous vasculitis.
- Symptoms of fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as hepatitis.

Please note that while taking Nitrofurantoin/IASIS, your urine may become dark yellow or brown coloured. This is absolutely normal and not a reason to stop taking the medicine.

**Other side effects are:**

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

- Loss of consciousness (faint).

**Not known (frequency cannot be estimated on the basis of the available data)**

- Feeling sick (nausea) and headache
- Diarrhoea
- Loss of appetite, stomachache and being sick (vomiting)
- Dizziness, sleepiness
- 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
- Short-term hair loss
- Urinary infection by germs which are not sensitive to Nitrofurantoin/IASIS.
- Inflammation of small blood vessel walls, causing skin lesions
- Liver inflammation due to the turning of the immune system against liver cells
- Inflammation of kidney tissue surrounding tubules, causing renal impairment, with frequency not known

**Reporting of side effects**

If you experience any side effects, tell your doctor, pharmacist or nurse. This also applies to any possible side effects not listed in this package leaflet.

You can also report side effects directly via the national reporting system:

**Cyprus Pharmaceutical Services**

Ministry of Health, CY-1475 Nicosia. Fax: + 35722608649, Site: [www.moh.gov.cy/phs](http://www.moh.gov.cy/phs)

**Malta Medicines Authority**

Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann, SGN 3000, Malta.

Tel: +356 23439000, Fax: +356 23439161 or [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)

By reporting side effects, you can contribute to the collection of more information on the safety of this medicine.

**5. How to store Nitrofurantoin/IASIS**

- Keep this medicine out of the sight and reach of children.
- Store in the original package in order to protect from light.
- After first opening, do not store at a temperature above 25°C and use it within 3 months.
- Do not use this medicine after the expiry date stated on the inner and outer package after EXPIRATION. The expiry date is the last day of that month mentioned therein.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Nitrofurantoin/IASIS contains**

The active substance is nitrofurantoin. Each 5ml of suspension contains 25mg of the nitrofurantoin (as monohydrate).

The other ingredients are methyl parahydroxybenzoate, propyl parahydroxybenzoate, polysorbate 20, glycerol, carbomer, sucralose, apricot flavour, sodium hydroxide, purified water.

**What Nitrofurantoin/IASIS looks like and contents of the pack**

Nitrofurantoin/IASIS is a yellow suspension with a characteristic apricot odour.

This medicine is provided in 300ml dark-coloured glass bottle with LDPE, child-resistant and tamper evident screw cap packed in a cardboard box containing a 5 ml plastic oral dosing syringe (graduated every 0.1 ml) and an adaptor for the syringe or one double plastic 2.5/5.0 ml measuring spoon.

**Marketing Authorisation Holder and Manufacturer**

IASIS PHARMACEUTICALS HELLAS S.A.

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