Package leaflet: information for the user

Nitrofurantoin
25mg/5ml Oral Suspension

nitrofurantoin

The name of your medicine is Nitrofurantoin 25mg/5ml Oral Suspension which will be referred to as 'Nitrofurantoin Oral Suspension' throughout this leaflet.

Read all of this leaflet carefully before you start using 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 or pharmacist.
- 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 ORAL SUSPENSION IS AND WHAT IT IS USED FOR

Nitrofurantoin (the active substance in Nitrofurantoin Oral Suspension) 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 ORAL SUSPENSION

Do not take this medicine:

- if you are **allergic** (causing itching, reddening of the skin or difficulty in breathing) to nitrofurantoin or any of the ingredients of this medicine (listed in section 6 at the end of the leaflet) or other medicines containing nitrofurantoin.
- if you have a **disease of the kidneys** which is severely affecting the way they work (ask your doctor if you are not sure).
- 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).

Do not give this medicine to children under three months of age.

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 Oral Suspension:

- if you have **diabetes.**
- if you are suffering from any illness causing **severe weakness.**
- if 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).
- if you have a history of **allergic reactions.**

The above conditions may increase the chance of developing a side effect which results in damage to the nerves, causing an altered sense of feeling such as pins and needles.

- if 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).
- if you have any **disease of the lungs, liver or nervous system**. If you need to take Nitrofurantoin Oral Suspension for a number of months, your doctor may want to regularly check how your lungs and liver are working.

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, or pain or discomfort when breathing. These may be symptoms of side effects affecting the lungs.

This medicine may interfere 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. 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 grey-coloured stools. It may be symptoms of liver disorder.

Other medicines and Nitrofurantoin Oral Suspension

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Tell your doctor or pharmacist if you are taking any of the following medicines as their effect may be changed or the effect of Nitrofurantoin Oral Suspension may be changed.

- Antacids for indigestion (e.g. magnesium trisilicate).
- Oral contraceptives ("the pill").
- 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 Oral Suspension with food and drink

Nitrofurantoin Oral Suspension should always be taken with food or milk. Taking this medicine with food or milk makes it work more effectively.

Pregnancy and breast-feeding and fertility

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 Oral Suspension 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 affect the baby. If you want to breast feed, please consult your doctor first.

Driving and using machines

Nitrofurantoin Oral Suspension may cause dizziness and drowsiness. You should not drive or operate machinery if you are affected this way until such symptoms go away.

Nitrofurantoin Oral Suspension contains:

- Methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).
- Glycerol which may cause headache, stomach upset and diarrhoea.
- Less than 1mmol sodium per dose, i.e. essentially sodium free.

3. HOW TO TAKE NITROFURANTOIN ORAL SUSPENSION

Follow your doctor's instructions exactly and **complete the course of the treatment even if you feel better**. You should check with your doctor or pharmacist if you are not sure.

Adults:

The normal dosage depends on the type of infection you have and 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 spoonfuls four times a day for seven days.
- For prevention of further infections: two to four 5ml spoonfuls to be taken once a day.
- For prevention of infections during surgery: two 5ml spoonfuls four times a day on the day of the operation and three days thereafter.

Children and infants aged over three months:

For children under 25kg body weight consideration should be given to the use of Nitrofurantoin Oral Suspension.

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

Children below 3 months of age should not take Nitrofurantoin Oral Suspension.

How to take this medicine:

This medicine should always be taken with food or milk. Taking this medicine with food or milk makes it work more effectively.

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 your specific dose.

How to use the plastic dosing syringe:

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

1. Shake the bottle well, making sure the cap is firmly on the bottle.
2. Remove the cap. Note: Keep the cap nearby to close the bottle after each use.
3. Push the plastic adaptor into the neck of the bottle. Note: The adaptor must always stay in 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 adaptor.
6. Turn the whole bottle with the syringe upside down.
7. Slowly pull the plunger down fully so that the syringe fills with medicine. Push the plunger back up completely to expel any large air bubbles that may be trapped inside the oral syringe.
8. Then pull the plunger slowly back to the volume you need for your dose.
9. Turn the whole bottle with the syringe the right way up 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 the plunger must be pushed slowly to allow you to swallow the dose.
11. Replace the child resistant cap after use, leaving the adaptor in place.
12. Cleaning: After use, wipe the outside of the syringe with a dry, clean tissue.

Medical Checks

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

Nitrofurantoin Oral Suspension may interfere with the results of some tests for glucose in the urine.

If you TAKE MORE Nitrofurantoin Oral Suspension than you should:

Consult your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any leftover medicine with you, as well as the container and label, so that the medical staff know what you have taken.

If you FORGET TO TAKE Nitrofurantoin Oral Suspension:

Do not worry. If you remember 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 a forgotten dose. If you are not sure, ask your doctor or pharmacist.

If you STOP TAKING Nitrofurantoin Oral Suspension:

Your doctor will tell you how long to 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, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most of them are mild and disappear when you stop taking Nitrofurantoin Oral Suspension.

All medicines can cause allergic reactions although serious allergic reactions are rare.

Stop taking this medicine and seek immediate medical help if you develop:

- **Signs of a serious allergic reaction such as:**
  - difficulty in breathing or any sudden wheeziness.
  - a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cell).
  - swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Stop taking this medicine and tell your doctor if you experience any of the following side effects:

- 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.
- 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, blurred 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 fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as hepatitis.

Please note that while taking Nitrofurantoin Oral Suspension your urine may become dark yellow or brown coloured. This is quite normal and not a reason to stop taking the medicine.

Tell your doctor if you have any of the following side effects, they become worse or you notice any effects not listed:

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

- Loss of consciousness (collapse).

Side effects for which the frequency cannot be estimated from available data:

- Feeling sick (nausea) and headache.
- Diarrhoea.
- Loss of appetite, stomach ache, and being sick (vomiting).
- Dizziness, drowsiness.
- 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 Oral Suspension.

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 website: 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 ORAL SUSPENSION

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions before opening.

After first opening, do not store above 25ºC and use within 3 months.

Do not use this medicine after the expiry date which is stated on the carton and bottle after 'EXP'. 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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nitrofurantoin Oral Suspension contains

The active substance is nitrofurantoin.

Each 5ml spoonful contains 25mg of nitrofurantoin (as monohydrate).

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

What Nitrofurantoin Oral Suspension looks like and contents of the pack

Nitrofurantoin Oral Suspension is a yellow suspension with a characteristic apricot odour.

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

Not all pack-sizes may be marketed.

Marketing Authorisation Holder

Aspire Pharma Ltd
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom

Manufacturer

IASIS Pharmaceuticals Hellas ABEE
137, Filis Ave.,
Kamatero, Attiki
13451
Greece

or

IASIS Pharmaceuticals Hellas S.A. - KOROPI
Archimidous Street
Koropi Attikis
19400
Greece

This leaflet was last revised in May 2023

1010490 - P3.2

ASPIRE® PHARMA