Package leaflet: Information for the user

Nitrofurantoin 25mg/5ml Oral Suspension

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

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2. What you need to know before you take Nitrofurantoin Oral Suspension
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1. What Nitrofurantoin Oral Suspension is and what it is used for

Nitrofurantoin monohydrate (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 Nitrofurantoin Oral Suspension:
- if you are allergic to Nitrofurantoin monohydrate, other nitrofurans or any of the other ingredients of this medicine (listed in section 6).
- 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)
- if your child is 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 or nurse 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
- if you have any problems with your kidneys
- if you have a lung disease. 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.

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 or 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.
- as 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.
- 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. 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.

If they are taken with Nitrofurantoin Oral Suspension, their effect or the effect of Nitrofurantoin Oral Suspension may be changed.

In particular, 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 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. This 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 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:

- Glycerol (E422): This medicine contains 525.0mg glycerol in each 5 ml, which may cause headache, stomach upset and diarrhoea.

- Methyl parahydroxybenzoate (E218): This medicine contains 6.0mg methyl parahydroxybenzoate per 5ml, which may cause allergic reactions (possibly delayed).
- Ethyl parahydroxybenzoate (E214): This medicine contains 2.5mg Ethyl parahydroxybenzoate per 5ml, which may cause allergic reactions (possibly delayed).
- Sodium: This medicine contains less than 1mmol sodium per 5 ml, that is to say essentially 'sodium-free'

3. How to take Nitrofurantoin Oral Suspension

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

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: 50-100 mg (10-20 ml) four times a day for seven days
- For prevention of further infections: 50-100 mg (10-20 ml) to be taken once a day
- For prevention of infections during surgery: 50 mg (10 ml) four times a day on the day of the operation and three days thereafter.

Use in children and infants aged over three months:
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.

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.

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

Please use the oral syringe provided to measure your dose.

How to use the oral syringe

1. Shake the bottle well before use (for at least 5 seconds).



2. Remove the cap by pushing down and turning it anti-clockwise.



3. When the medicine is used for the first time, the plastic adapter must be inserted firmly into the neck of the bottle.



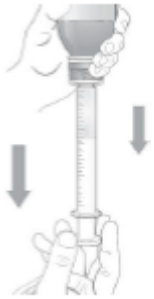
4. Take the syringe and check the plunger is fully down.
   Keep the bottle upright and insert the syringe firmly into the plastic adapter.



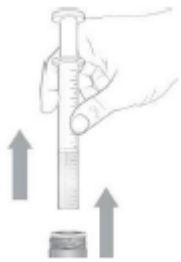
5. Turn the bottle with the syringe upside down.



6. Slowly pull the plunger down and the medicine should be drawn to the required dose on the syringe.



7. Turn the bottle (with the syringe) the right way up and take the syringe out of the bottle.



8. 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.



9. Replace the child resistant cap after use, leaving the adapter in place.



10. After use, dismantle the syringe and rinse both the body and plunger with warm water. Wipe with a dry, clean tissue or paper.



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 left over 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. If you notice 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 or any other side effects, stop taking Nitrofurantoin Oral Suspension and consult your doctor.

- Your lungs may react to Nitrofurantoin Oral Suspension. This may develop quickly, within a week of starting treatment or very slowly, especially in elderly patients. This may produce fever, chills, cough and shortness of breath. Scaring due to damaged lung tissue may occur.
- 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 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. In rare cases, it may cause liver failure which may be fatal.

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.

Other side effects include:

Rare: may affect up to 1 in 1,000 people

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

Not known: frequency cannot be estimated from the 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 25mg/5ml Oral Suspension.
- 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 tubules, causing renal impairment

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 MHRA 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.
Store in the original container in order to protect from light and moisture.
Do not store above 30°C. Do not freeze.
Do not use this medicine after the expiry date which is stated on the label after EXP: The expiry date refers to the last day of that month.
Use within 30 days of first opening.
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 monohydrate. Each 5 ml contains 25 mg of nitrofurantoin monohydrate.

The other ingredients are Glycerol (E422), Carbopol (Carbomer) 974P, Polysorbate 20, Sodium saccharin (E954), Sucralose, Methyl parahydroxybenzoate (E218), Ethyl parahydroxybenzoate (E214), Apricot flavour containing propylene glycol (E1520), Sodium hydroxide (E524), Hydrochloric acid (E507), Purified water

What Nitrofurantoin Oral Suspension looks like and contents of the pack:
This medicine is a yellow, homogenous suspension, supplied in amber glass bottles sealed with a polypropylene child-resistant, tamper evident cap. A 5 ml plastic dosing syringe is included in the carton with a syringe adaptor.

Marketing Authorisation Holder and Manufacturer:
Aristo Pharma GmbH
Wallenroder Strasse 8-10
13435 Berlin
Germany

This leaflet was last revised in 02/2026.

If you are blind or partially sighted and require this leaflet in a different format, call 01483 920754 or contact medinfo@aristo-pharma.co.uk