Package leaflet: Information for the patient
Furadantin® 50mg tablets
Furadantin® 100mg tablets
nitrofurantoin

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 of the 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 Furadantin
3. How to take Furadantin
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1. What Furadantin is and what it is used for

Nitrofurantoin is an antibacterial agent which is used to prevent and treat infections of the bladder, kidneys and other parts of the urinary tract.

2. What you need to know before you take Furadantin

Do not take Furadantin:

- If you are allergic (causing itching, reddening of the skin or difficulty in breathing) to nitrofurantoin, other nitrofurans or any of the other ingredients of this medicine (listed in Section 6)
- If you have been advised by your doctor that you have a low kidney function (eGFR less than 45ml per minute)
- If you are in labour or delivering your baby or breastfeeding
- If you are suffering from porphyria (group of blood disorders that affect the nervous system or skin, or both)
- If you have lack of 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, Near Eastern or Asian origin, speak with your doctor about this) Furadantin should not be given to infants less than 3 months of age.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Furadantin:

- If you have a problem with your blood sugar (diabetes mellitus)
- If you are suffering from any disease of lungs, liver or nervous system (If you need to take Macrodantin Furadantin for a number of months, your doctor may want to regularly check how your lungs and liver are working)
- If you have symptoms of numbness or weakness in the extremities (peripheral neuropathy)
- If you have any kidney problem (You have an eGFR between 30-44 ml/min as your doctor may consider using this medicine after considering the benefit and risk)
- If you have previously experienced an allergic reaction to a drug
- If the concentration of your body salts needs adjustment (electrolyte imbalance) or you lack vitamin B (particularly folate)
- If you have anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness)
- If you have diarrhoea caused by a bacteria known as clostridium difficile
- If you are taking any other antibacterial medicines
- If you are taking other medicines listed in the next section.
- 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 Furadantin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Do not take Furadantin without talking to your doctor or pharmacist first, if you are taking:

• Antacids (e.g. magnesium trisilicate)
• Medicines for gout (e.g. probenecid or sulfinpyrazone)
• Medicines for glaucoma: such as carbonic anhydrase inhibitors (e.g. acetazolamide). These are mild "water tablets" which are usually prescribed when the pressure in the eye ball is raised (glaucoma)
• Medicines which make the urine less acid (e.g. potassium citrate mixture)
• Medicines for infections (antibiotics) known as Quinolones
• Typhoid vaccine, which is given for the prevention of typhoid
• Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine).

Medical checks

Your doctor will watch carefully for any effects on the liver, lungs, blood or nervous system, especially if you are elderly or are taking Furadantin for a long time. Furadantin may interfere with the results of some tests for glucose in the urine.

Furadantin with food and drink

Furadantin should be taken at meal times with food or milk. 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.

Furadantin may be used in pregnancy except at term and during labour and delivery.

This medicine should be avoided in mothers who are breast-feeding.

Driving and using machines
Furadantin may cause dizziness and drowsiness. You should not drive or operate machinery if you are affected this way until such symptoms go away.

Furadantin contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Furadantin

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

Adults and children over 10 years old:
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. Typical doses are:
For treatment of infections: Either a 50mg tablet or a 100mg tablet four times a day for seven days.
For prevention of further infections: Either a 50mg tablet or a 100mg tablet at bedtime.
For prevention of infections during surgery: A 50mg tablet four times a day on the day of the procedure and three days thereafter.

Use in children
Children aged over three months:
The dosage 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 Furadantin

Method of administration
Take Furadantin with food or milk.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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

If you forget to take Furadantin

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 tablet. If you are not sure, ask your doctor or pharmacist.

If you stop taking Furadantin
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 Furadantin.

If you experience any of the side effects detailed below or any other side effects, stop taking Furadantin and consult your doctor.

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.

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

If you notice any of the following side effects consult your doctor immediately:
• A group of blood disorders that affect the nervous system or skin, or both (Acute porphyria)
• Your lungs may react to Furadantin. 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.• Furadantin may cause the liver to become inflamed, producing jaundice (yellowing of the skin or whites of the eyes), fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as drug induced autoimmune hepatitis. In rare cases, it may cause liver failure which may be fatal.
• Raised pressure in the skull (causing severe headaches).
• Blue or purple coloration 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, skin symptoms such as lesions e.g. palpable purpura and petechiae. These could be signs of a condition known as cutaneous vasculitis.

Other side effects include
Rare: may affect up to 1 in 1,000 people
- Damage to bone marrow causing deficiency of the red blood cells (Anaemia)
- Loss of consciousness (collapse)

Not known: Frequency cannot be estimated from the available data
• 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
• Feeling sick (nausea) and headache
• Loose stools
• Loss of appetite, stomach ache and being sick (vomiting)
• Diarrhoea
• Dizziness, drowsiness
• 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 (psychosis), 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 may slightly blur vision) may occur. These effects may be severe and in some instances permanent
• A variety of skin rashes or reactions have occurred in some patients. Cases of a severe form of drug reaction with involvement of skin and other parts of the body (DRESS syndrome) are also reported.
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.
• Fatigue, chills and drug fever• Short-term hair loss
• Urinary infection by germs which are not sensitive to Furadantin.
• 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
• Furadantin may interfere with the results of some tests for glucose in the urine

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-

HPRA Pharmacovigilance,
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furadantin

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label and carton afterEXP. The expiry date refers to the last day of that month. Do not store above 25°C. Store in the original container and keep the container tightly closed in order to protect from light and moisture. Keep the container in the outer carton.
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 Furadantin contains
The active substance is nitrofurantoin. Each tablet contains 50 mg or 100 mg of nitrofurantoin. The other ingredients are lactose monohydrate, maize starch, talc, alginic acid and magnesium stearate.

What Furadantin looks like and contents of the pack
Furadantin 50mg Tablets are yellow, pentagonal tablets imprinted with a monogram '50' on one face and a single breakline on the opposite face.
Furadantin 100mg Tablets are yellow, pentagonal tablets imprinted with a monogram '100' on one face and a single breakline on the opposite face.
Furadantin is available in bottles of 100 tablets.

Marketing Authorisation Holder
Amdipharm Limited, Temple Chambers, 3 Burlington Road, Dublin 4, Ireland.

Manufacturer
Custom Pharmaceuticals Limited, Conway Street, Hove, East Sussex, BN3 3LW, UK.

This leaflet was last revised in February 2021.

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