Package leaflet: Information for the patient
Macrodantin® 50mg and 100mg Capsules, hard
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.

The name of your medicine is Macrodantin 50mg and 100mg Capsules, hard.
It will be referred to as Macrodantin Capsules for ease hereafter.

What is in this leaflet:

1. What Macrodantin Capsules are and what they are used for
2. What you need to know before you take Macrodantin Capsules
3. How to take Macrodantin Capsules
4. Possible side effects
5. How to store Macrodantin Capsules
6. Contents of the pack and other information

1. What Macrodantin Capsules are and what they are used for

Nitrofurantoin (the active substance in Macrodantin Capsules) is an antibiotic. It is used to prevent and treat infections of the bladder and lower urinary tract.

2. What you need to know before you take Macrodantin Capsules

Do not take Macrodantin Capsules:

- If you are allergic to nitrofurantoin or any of the ingredients of this medicine (listed in Section 6)
- If you are allergic to other nitrofuran
- 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 the final stages of pregnancy (labour or delivery) or breast-feeding or in babies under three months of age, as there is a risk that it might affect the baby
- 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 know that you have a condition called porphyria group of blood disorders that affect the nervous system or skin, or both.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Macrodantin Capsules:
• If you have diabetes
• If you have any kidney problems (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 symptoms of numbness or weakness in the extremities (peripheral neuropathy)
• 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, causes altered sense of feeling, and pins and needles.
• If you have any disease of the lungs, liver or nervous system. If you need to take Macrodantin Capsules for a number of months, your doctor may want to regularly check how your lungs and liver are working
• If you are an elderly patient
• If you have diarrhea caused by a bacteria known as clostridium difficile
• If you are taking any other antibacterial medicines.
• 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 Macrodantin Capsules:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If the following medicines are taken with Macrodantin Capsules their effect or the effect of Macrodantin Capsules may be changed:
• Magnesium trisilicate (an antacids used for indigestion)
• Medicines for gout (e.g. probenecid or sulfinpyrazone)
• Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine)
• Medicines for glaucoma: such as carbonic anhydrase inhibitors (e.g. acetazolamide).
• Medicines known as urine alkalizing agents which make the urine less acid (e.g. potassium citrate mixture)
• Medicines for infections, known as quinolones
• Typhoid vaccine when taken by mouth.

Macrodantin Capsules with food and drink
Macrodantin Capsules should be taken 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.
As far as is known Macrodantin Capsules 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.

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

Macrodantin Capsules contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How to take Macrodantin Capsules

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

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

Do not forget to take your medicine.
Capsules should be swallowed whole.

Use in children (over 10 years)
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: One 50mg capsule four times a day for seven days
• For treatment of severe chronic recurrent infections: One 100mg capsule four times a day for seven days
• For prevention of further infections: Either one 50mg capsule or one 100mg capsule at bedtime
• For prevention of infections during surgery: One 50mg capsule four times a day on the day of the operation and for three days thereafter.

Use in children and infants (over three months of age)
The dose depends on the weight of the child and will be provided by your doctor. Follow your doctor's instructions exactly.

Use in children (below 3 months of age)
Children below 3 months of age should not take Macrodantin Capsules.

Method of administration
Macrodantin Capsules should be taken at meal times with food or milk.

Medical Checks:
Your doctor will watch carefully for any effects on the liver, lungs, blood or nervous system.
Macrodantin Capsules may interfere with the results of some tests for glucose in the urine.

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

If you forget to take Macrodantin Capsules
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 capsule. If you are not sure, ask your doctor or pharmacist.

If you stop taking Macrodantin Capsules:
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 Macrodantin Capsules.
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 stop taking Macrodantin Capsules and consult your doctor.
• A group of blood disorders that affect the nervous system or skin, or both (Acute porphyria)
• Your lungs may react to Macrodantin Capsules. This may develop quickly, within a week of starting treatment or very slowly, especially in elderly patients. This may produce fever, chills, cough, shortness of breath, collapse or a blue colouring to your skin. Scaring due to damaged lung tissue may occur.
• Jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes). Liver failure which may be fatal may also occur
• The nerves outside the spinal cord may be affected causing changes to the sense of feeling and the use of muscles. Treatment should be stopped at the first signs of a tingling sensation or numbness in the hands or feet. In addition headache, extreme changes of mood or mental state, confusion, weakness, drowsiness or blurred vision may occur. These effects may be severe and in some instances permanent
• 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, diarrhea, blood in your stool and weakness. These could be signs of a condition known as cutaneous vasculitis.
• Symptoms of jaundice, fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as autoimmune hepatitis.

Please note that while taking Macrodantin Capsules your urine may become coloured dark yellow or brown. 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
• Damage to bone marrow causing deficiency of the red blood cells (Anaemia)

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
• Diarrhoea (Loose stools)
• Loss of appetite, stomach ache, and being sick
• 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
• 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
• Fatigue, chills and drug fever
• Short-term hair loss
• Urinary infection by germs which are not sensitive to Macrodantin Capsules.
• 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 Macrodantin Capsules

Keep this medicine out of the sight and reach of children.
Do not store above 30°C. Store in the original package in order to protect from light and moisture.
Do not use this medicine after the expiry date which is stated on the carton (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 Macrodantin Capsules contains
The active substance is Nitrofurantoin. Macrodantin Capsules are available in two strengths, containing either 50 mg or 100 mg Nitrofurantoin.
The other ingredients are talc, maize starch, lactose monohydrate. The capsule shell contains gelatin, sodium lauril sulfate and colourings quinoline yellow (E104) and titanium dioxide (E171). The printing ink contains shellac and black iron oxide (E172).
What Macrodantin Capsules looks like and contents of the pack:
Macrodantin 50mg capsule is a hard gelatin capsule with an opaque yellow cap and opaque white body containing a pale yellow powder. The capsules are printed in edible black ink and bear the monogram "Eaton 008".
Macrodantin 100mg capsule is a hard gelatin capsule with an opaque yellow cap and body containing a pale yellow powder. The capsules are printed in edible black ink and bear the monogram "Eaton 009".

The capsules are available in blister packs of 30.

Marketing Authorisation Holder:
Amdipharm Limited
Unit 17, Northwood House
Northwood Crescent
Northwood
Dublin 9
D09 V504
Ireland

Manufacturer: Lusomedicamenta S.A., Sociedade Técnica Farmacêutica, Estrada Consiglieri Pedroso, 69-B, Queluz de Baixo, 2730-055 Barcarena, Portugal.

This leaflet was last revised in October 2026

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