

Patient Information Leaflet (PIL)

Uvamin™ 100 mg retard capsules

Nitrofurantoin

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Uvamin™ is and what it is used for

Uvamin™ 100 mg retard capsules contain 100 mg of nitrofurantoin. Nitrofurantoin is an antibacterial agent. Uvamin™ 100 mg retard capsules are used for acute and chronic urinary tract disorders caused by nitrofurantoin-sensitive organisms (e.g. cystitis, infections of the renal pelvis). It may also be used to prevent infections during examinations (e.g. cystoscopy) or after urinary tract surgery. Uvamin™ 100 mg retard must be used on medical prescription only.

2. Before you take Uvamin™

a. Do not take Uvamin™

Do not take Uvamin™ 100 mg retard:

- 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 have little or no urine output,
- if you have a nervous system disease such as peripheral neuropathy (polyneuropathy) or inflammation of a peripheral nerve or nerve in the brain (neuritis),

- if you have a rare hereditary red blood cell disease known as “glucose-6-phosphate dehydrogenase deficiency”,
- a specific lung disease (pulmonary fibrosis),
- if you have a disorder affecting the production of the red pigment in blood (acute porphyria),
- if you have a known allergy to nitrofurantoin or to any of the other ingredients of this medicine (listed in Section “6. Further information”). The manifestations of such hypersensitivity include, for example, asthma, shortness of breath, circulatory disorders, swellings of the skin (e.g. nettle rash) and mucous membranes or skin rashes.
- if you are in the final stages of pregnancy (labour or delivery) as there is a risk that it might affect the baby,
- if your child under three months of age,
- if you are breast feeding a baby with suspected or known deficiency in an enzyme called G6PD (glucose-6-phosphate dehydrogenase).

Uvamin™ 100 mg retard capsules are not recommended for use in children below 12 years.

b. Take special care with

Talk to your doctor before taking Uvamin™ 100 mg retard if any of the side effects listed below (see “4. Possible side effects”) have occurred during previous treatment with nitrofurantoin (the active substance in Uvamin™ 100 mg retard). In particular, liver and skin symptoms must be mentioned. You must inform your doctor if you have any problems with your kidneys, if you suffer from any disease of the lungs, liver or nervous system, if you have anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness), diabetes, motor weakness or vitamin B deficiency. If you need to take Uvamin™ 100 mg retard for a number of months, your doctor may want to regularly check how your lungs and liver are working.

Tell your doctor if you lack an enzyme (body chemical) called glucose-6-phosphate dehydrogenase, which causes your red blood cells to be more easily damaged.

c. Taking other medicines

Your doctor must be informed if you are taking certain medicines for infections, e.g. those containing the active substance nalidixic acid, medicines that increase uric acid excretion (anti-gout medicines) containing the active substances sulphinpyrazone or probenecid, medicines containing the active substance phenytoin, used to treat convulsive disorders (epilepsy) or medicines containing propantheline, used to block stomach acid secretion.

As co-administration of certain antacids (medicines used to treat excess stomach acid) reduces nitrofurantoin absorption, nitrofurantoin must be administered at least one hour before the antacids.

Tell your doctor or pharmacist if you are taking, have recently taken or might take typhoid vaccine, which is given for the prevention of typhoid.

Nitrofurantoin blocks the antibacterial action of certain other medicines used to treat urinary tract infections.

As with other antibiotics, nitrofurantoin can compromise the intestinal flora, which leads to reduced effectiveness of certain contraceptives. Additional contraceptive precautions must be used.

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

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.

Inform your doctor or pharmacist if you

- suffer from any other illnesses
- have any allergies or
- are taking any other medications (including non-prescription medications).

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

d. 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 Uvamin™ 100 mg retard may be used in pregnancy. However, it should not be used during final stages of pregnancy (labour and 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.

Ask your doctor for advice before taking any medicine.

e. Driving and using machines

This medicine may alter responsiveness to such an extent that the ability to drive and use tools or machines is impaired. Uvamin™ 100 mg retard may cause dizziness. You should not drive or operate machinery until symptoms go away.

f. Important information about some of the ingredients of Uvamin™

This medicine contains lactose. If you have been told by your doctor that you are intolerant to some sugars and have to avoid them, contact your doctor before taking this medicine.

3. How to take Uvamin™

Always take Uvamin™ 100 mg retard exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide on the dose of Uvamin™ 100 mg retard. Unless otherwise prescribed by the doctor, the following indications apply:

Adults

Acute urinary tract infections

Take one capsule 2-3 times daily for 7-10 days.

Long-term treatment of chronic urinary tract infections

Take one capsule 1-2 times daily.

Children below 12 years of age

Uvamin™ 100 mg retard capsules are not recommended for use in children below 12 years.

The prolonged-release capsules should be swallowed whole without chewing. Take with plenty of liquid at mealtimes.

Once started, treatment with Uvamin™ 100 mg retard should be continued for the entire duration prescribed by the doctor. Do not change the daily dose or the duration of treatment without consulting your doctor or pharmacist. Symptoms of disease often disappear before the infection is completely cured. If the treatment period is too short or if treatment is ended too early, the infection may flare up again.

Do not change the prescribed dosage of your own accord. If you think the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

If you take more Uvamin™ than you should

If you take too much Uvamin™ 100 mg retard contact your doctor or your nearest hospital emergency department immediately. If possible, show them the Uvamin™ 100 mg retard pack, so that the medical staff knows what you have taken.

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

4. Possible side effects

Like all medicines, Uvamin™ 100 mg retard can cause side effects, although not everybody gets them.

If you notice the following symptoms, stop treatment with Uvamin™ 100 mg retard immediately and inform your doctor without delay:

- sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body). These are the signs of serious allergic reactions. Hypersensitivity reactions (severe allergic reactions) that may develop into dangerous shock (signs of shock include cold sweating, wheezing, drop in blood pressure, racing heart, dizziness and light-headedness) (anaphylactic shock).
- bullous skin reactions such as Stevens-Johnson syndrome or toxic epidermal necrolysis (potentially life-threatening). Signs of a bullous skin reaction include severe impairment in the general state of health, joint pain, fever, painful blisters in the mouth, throat and genital region, severe conjunctivitis.

- abnormal sensations in the hands and/or feet, headache, dizziness, extreme changes of mood or mental state (depression, euphoria, confusion or other psychotic reactions), weakness, blurred vision or nystagmus (uncontrollable, rhythmic movements of an organ, most commonly the eye). These neurological effects may be severe and in some instances permanent;
- your lungs may react to nitrofurantoin. This may develop quickly, with sudden shortness of breath, cough, fever and pain behind the breastbone, or slowly with the listed symptoms (including the sensation of breathlessness in the recumbent position, relieved by sitting or standing), especially in elderly patients;
- jaundice (yellowing of the skin or whites of the eyes), especially accompanied by fatigue, abdominal pain, joint pain and swelling as signs of liver inflammation (autoimmune hepatitis).
- raised pressure in the skull (causing severe headaches);
- severe reduction in blood cells which can cause weakness, bruising or make infections more likely;

The following side effects may occur during the treatment with Uvamin™ 100 mg retard:

Common (may affect up to 1 in 10 people)

- Feelings of dizziness
- Headache
- Allergic skin reaction
- Fever

Uncommon (may affect up to 1 in 100 people)

- peripheral neuropathy (changes to the sense of feeling and the use of muscles, blurred vision, confusion, extreme changes of mood or mental state, , weakness, , somnolence)
- nystagmus (uncontrollable, rhythmic movements of an organ, most commonly the eye)
- allergic lung reaction (called nitrofurantoin pneumonia) with episodes of coughing, shortness of breath and chest pain, particularly during long-term therapy
- vomiting (being sick)
- stomach pain
- diarrhea

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

- a decrease in the number of blood cells (agranulocytosis, eosinophilia, leukopenia, granulocytopenia, glucose-6-phosphatedehydrogenase deficiency anaemia, haemolytic anaemia, thrombocytopenia and megaloblastic anaemia, aplastic anaemia)
- inflammation of the pancreas – signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- liver disorders (yellowing of the whites of the eyes or skin and inflammation of the liver)
- erythema nodosum (inflammation of the fat cells under the skin, resulting in red nodules)
- temporary hair loss
- increased occurrence of crystals in the urine sediment (crystalluria)
- reversible disorders of spermatogenesis
- parotitis
- loss of appetite (and even anorexia)

Very rare (may affect up to 1 in 10,000 people)

- outbreaks of sweating
- feeling of weakness
- globus symptoms ("lump in the throat" sensation)

Not known (cannot be estimated from the available data)

- lupus-like syndrome (reversible autoimmune disorder)
- hypersensitivity reactions, including anaphylaxis, drug fever and joint pain
- benign intracranial hypertension (raised pressure in the skull causing severe headaches)
- feeling sick (nausea)
- additional infections caused by microorganisms which are not sensitive to nitrofurantoin
- cutaneous vasculitis
- autoimmune hepatitis

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please stop taking this medicine and tell your doctor or pharmacist.

5. How to store Uvamin™

Keep out of the reach and sight of children.

Do not store above 30 °C.

Uvamin™ 100 mg retard may be used only up to the date marked with “EXP” on the pack.

Once you have finished treatment, take the remaining medicine to your dispenser (doctor or pharmacist) for correct disposal.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information**a. What Uvamin™ contains**

The active substance is nitrofurantoin.

Each capsule of Uvamin™ 100 mg retard contains 100 mg of nitrofurantoin.

The other ingredients are:

Capsule fill: hypromellose, lactose monohydrate, cellulose microcrystalline, purified water.

Capsule shell: hard gelatin capsule shell, gelatine, quinoline yellow, titanium dioxide.

b. What Uvamin™ looks like and content of the pack

Uvamin™ 100 mg retard is hard gelatin capsule, size No 2, with yellow cap and body, and the imprint “100”.

Uvamin 100 mg retard capsules are packed in PVC/PVDC – Aluminium blisters, which are packed in carton box.

Each pack contains 2 blisters each of 10 capsules.

c. Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder/ Manufacturer/ Batch releaser
Acino Pharma AG, Liesberg, Switzerland

This leaflet was last revised in November 2019.

To report any side effect (s):

- **Saudi Arabia:**

- The National Pharmacovigilance and Drug Safety Center (NPC):
 - o Fax: +966-11-205-7662
 - o Call NPC at 8002490000 (free phone)
 - o SFDA call center: 19999
 - o E-mail: npc.drug@sfda.gov.sa
 - o Website: www.sfda.gov.sa/npc

- Acino Pharma Scientific Office:
 - o Phone: +966-11-4631459
 - o E-mail: pv@acino.swiss

- **Other GCC states**

Please contact the relevant competent authority

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
and Union of Arab Pharmacist