**Bijsluiter: informatie voor de patiënt**

**Nitrofurantoine Adalvo 100 mg harde capsules met gereguleerde afgifte**
nitrofurantoine

**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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Nitrofurantoin Adalvo is and what is it used for

This medicine belongs to the group of nitrofurans. The active ingredient in Nitrofurantoin Adalvo works by killing most of the bacteria that cause urinary tract infections.
This medication is used to treat acute (sudden onset) urinary tract infections. Urinary tract infection is an inflammation of the urinary tract and particularly common is the infection of the bladder (cystitis). These infections may cause discomfort such as pain and burning when urinating, often the evacuation of small amounts of urine and pain in the lower abdomen.

## 2. What do you need to know before you take Nitrofurantoin Adalvo

**Do not take Nitrofurantoin Adalvo:**
- if you are allergic to nitrofurantoin 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 have porphyria (reduced formation of red pigment in the blood).
- if you have G6PD (glucose-6-phosphate dehydrogenase) deficiency (deficiency of a certain body chemical enzyme, which can quickly damage your red blood cells).
- if you have previously had a lung or liver reaction or peripheral neuropathy (tingling, numbness or weakness in the limbs) when taking nitrofurantoin or other nitrofurans.
- do not use Nitrofurantoin Adalvo in infants under 3 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 Adalvo

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 gray-colored stools. It may be symptoms of liver disease.

Long-term treatment, especially in the elderly, requires regular medical supervision. This is to timely detect any side effects.

Some black people of Black descent and people of Mediterranean, Near Eastern may develop anaemia during treatment. If you belong to this group and you develop tiredness, dizziness and shortness of breath during treatment, stop taking the medicine and contact your doctor.

If you experience tingling or numbness in the hands or feet or weakness in the limbs during treatment, stop taking the medicine and contact your doctor. This is more likely if, for example, your kidneys are not working properly, if you have diabetes or anaemia, if you have an illness that causes severe weakness or if you have previously had allergic reactions.

Complications in the lungs or liver can occur: see "**Possible side effects**". If such complications arise, the use of this medicine should be discontinued immediately.

**Other medicines and Nitrofurantoin Adalvo**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and other medicines that you buy without a prescription. Some of these medicines can change the effect of Nitrofurantoin Adalvo.
- antacids containing magnesium trisilicate may reduce the absorption of nitrofurantoin.
- tell your doctor if you are taking an anti-gout medicine such as probenecid and sulfinpyrazone. Some of these medicines can reduce the effect of Nitrofurantoin Adalvo.
- if you are prescribed a quinolone antibacterial agent, tell the doctor that you are also taking this medicine. Combining these agents can reduce the effectiveness of both.
- carbonic anhydrase inhibitors (such as acetazolamide for the treatment of glaucoma).
- the oral typhoid vaccine may not work when you are taking this medicine. Discuss this with your doctor.
- medicines that slow down the passage of food through the stomach (such as atropine, hyoscine).
- medicines that make the urine less acidic (such as potassium citrate mixture).
- urine glucose tests can be affected by this medicine.

If you are not sure about any of these medicines, consult your doctor or pharmacist.

**Nitrofurantoin Adalvo with food and drink**
Nitrofurantoin Adalvo should be taken at meal times with food or with a dairy product, such as milk or yogurt. This will help to avoid stomach upset and also to facilitate the absorption.

**Pregnancy, breastfeeding and fertility**
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

***Pregnancy***
As far as it is known, nitrofurantoin may be used during pregnancy. However, this medicine should not be used during labour and delivery because there is a possibility that use at this stage may affect the baby. Always follow your doctor's instructions carefully.

***Breastfeeding***
If you wish to breastfeed, consult your doctor first because this medicine passes into breast milk and may pose a hazard to infants under 3 months of age.

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

**Nitrofurantoin Adalvo contains lactose and sucrose**
This medicine contains lactose and sucrose which are types of sugars. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## 3. How to take Nitrofurantoin Adalvo

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

Nitrofurantoin Adalvo is to be taken by mouth: the capsule should be swallowed whole, with a meal or with some milk or yogurt. Thus, this medicine is better tolerated and also gives better results.

The recommended dose for adults and children over 12 years is two capsules per day, 1 capsule in the morning and 1 in the evening (1 capsule every 12 hours). Preferably take the capsule in the evening just before going to bed, after the last urination.

The general use is one capsule twice a day for 7 days. However, always follow your doctor's instructions carefully.

When a treatment is started, the symptoms may diminish quickly, usually within half of a day to 2 days, and then disappear completely. Nevertheless, the prescribed treatment must be followed completely. After all, the inconveniences can disappear, but this does not mean that all bacteria have already been killed. If you stop too soon, the infection may return quickly, which is unpleasant for you and medically undesirable. If the discomfort has not disappeared after 3 days of treatment, please contact your doctor.

**Use in children**
This medicine is not suitable for children under 12 years of age.

**If you take more Nitrofurantoin Adalvo than you should**
Contact your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any remaining capsules with you, as well as the container and label, so that the medical staff know what you have taken. Vomiting and gastrointestinal upsets may occur when you take too much medication.

**If you forget to take Nitrofurantoin Adalvo**
Normally you should take one capsule twice a day. If you miss a dose, take it as soon as possible. If it is almost time for the next dose, skip the forgotten dose and go back to your regular schedule. Do not take a double dose to make up for a forgotten capsule.
If you have forgotten several doses in a row, please contact your doctor. He will probably prescribe a new treatment.

**If you stop taking Nitrofurantoin Adalvo**
If you stop the treatment too soon, the symptoms may return very quickly, and this may be undesirable and unpleasant for you. That is why it is important that you complete the treatment.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of them are mild and usually disappear when you stop taking Nitrofurantoin Adalvo. If you experience any of the side effects detailed below, or any other side effects, stop taking this medicine and consult your doctor or pharmacist.

All medicines can cause allergic reactions, although serious allergic reactions are rare. If you experience 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 see a doctor immediately.

Be aware that your urine may become coloured dark yellow or brown while taking Nitrofurantoin Adalvo. This is quite normal and it not a reason to stop taking the medicine.

If you notice any of the following side effects, see your doctor immediately:
- your lungs may react to Nitrofurantoin Adalvo. This may develop quickly, within a week of starting treatment or very slowly, especially in elderly patients. This can lead to fever, chills, cough, and shortness of breath associated with pneumonia and tissue damage.
- this medicine may cause the liver to become inflamed, producing jaundice (yellowing of the skin or whites of the eyes). This can rarely happen.
- blood cells are affected in some patients, causing bruising, slowed blood clotting, sore throat, fever, anaemia and susceptibility to cold or persistent cold.
- increased pressure in the skull (causing severe headache).
- severe allergic skin reactions (DRESS-syndrome).
- several skin reactions have been reported, such as peeling skin, red skin rash or fever accompanied by increased heart rate and severe blistering rash.

**Very common (may affect more than 1 in 10 people):**
- urinary tract infection due to bacteria that are not sensitive to Nitrofurantoin Adalvo.
- short-term hair loss.

**Rare (may affect up to 1 in 1,000 people):**
- loss of appetite.
- feeling sick (nausea).
- loss of consciousness (collapse).
- bluish or grayish color of the skin, nails, lips or around the eyes (cyanosis).

**Not known (frequency cannot be estimated from the available data):**
- headache.
- diarrhoea.
- stomach ache and being sick (vomiting).
- dizziness, drowsiness.
- nerves can be affected resulting in 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.
- a feeling or state of intense excitement and happiness (euphoria).
- other reactions may include inflammation of salivary glands (causing facial pains), inflammation of the pancreas gland (causing severe abdominal pain) and joint pains.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Nitrofurantoin Adalvo

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

Do not store Nitrofurantoin Adalvo above 25 °C.

Do not use this medicine after the expiry date (EXP) which is stated on the carton and/or blister. The expiry date refers to the last day of that month.

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. Contents of the package and other information

**What Nitrofurantoin Adalvo contains**

- The active substance is nitrofurantoin. Each capsule contains 100 mg of nitrofurantoin: 25 mg of nitrofurantoin in the macrocrystalline form and 80.7 mg of nitrofurantoin in the form of monohydrate, corresponding to 75 mg of anhydrous nitrofurantoin.
- The other ingredients are:
    - capsule content: talc (E 553b), maize starch, carbomer 971P, povidone K30 (E 1201), lactose monohydrate, sucrose (see section 2 **Nitrofurantoin Adalvo contains lactose and sucrose**), magnesium stearate (E 470b).
    - capsule shell: iron oxide yellow (E 172), iron oxide black (E 172), titanium dioxide (E 171), Indigo Carmine (E 132), gelatin.
    - printing ink: shellac (E 904), propylene glycol (E 1520), strong ammonia solution (E 527), water, potassium hydroxide (E 525), titanium dioxide (E 171).

**What Nitrofurantoin Adalvo looks like and contents of the pack**

Nitrofurantoin Adalvo modified-release capsules are 19.4 mm long and 6.91 mm wide capsules with blue opaque cap imprinted with “NTRF” in white ink and yellow opaque body.

Nitrofurantoin Adalvo is supplied in carton boxes containing 2, 14 or 20 capsules in PVC-Aclar/aluminium blisters.

Not all pack sizes may be marketed in your country.

**Houder van de vergunning voor het in de handel brengen en fabrikant**

Vergunninghouder:
Adalvo Limited
Malta Life Science Park,
Level 1, Building 4,
Sir Temi Zammit Buildings,
San Gwann, SGN 3000,
Malta

Fabrikant:
Pharmadox Healthcare Limited
KW20A Kordin Industrial Park
Paola, PLA 3000
Malta

**Dit medicijn is in het register ingeschreven onder:**

RVG 129327

**Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**

| | |
|---|---|
| Letland | Nitrofurantoin Adalvo 100 mg modificētās darbības cietās kapsulas |
| Nederland | Nitrofurantoine Adalvo 100 mg harde capsules met gereguleerde afgifte |

**Deze bijsluiter is voor het laatst goedgekeurd in maart 2023**