

Nitrofurantoin 50mg, 100mg capsules

What is Nitrofurantoin and what is it used for?

Nitrofurantoin belongs to the group of nitrofurans, a specific group of antibiotics (antibacterial agents). The active ingredient in this medication kills a large number of bacteria that cause urinary tract infections (including bladder infections).

This medication is used for:

Treating acute (sudden-onset) urinary tract infections. A urinary tract infection is an inflammation of the urinary tract; bladder infection, in particular, is very common. Such an infection can cause symptoms such as pain and a burning sensation during urination, frequent urination in small amounts, and pain in the lower abdomen.

Preventing infections, for example, when a urinary catheter is inserted or when surgery on the urinary tract needs to be performed.

Long-term treatment (up to 6 months) of persistent urinary tract infections that cannot be treated with other medications.

When should you not use this medication or be extra cautious?

When should you not use this medication?

- You are allergic to any of the substances in this medicine. You can find these substances in section 6 of this leaflet.
- You are allergic to another antibiotic belonging to the nitrofuran group.
- If your kidneys are not functioning properly (consult your doctor if you are unsure).
- If you have acute porphyria (a hereditary disorder in the production of red blood pigment).
- If you have G6PD deficiency (glucose-6-phosphate dehydrogenase deficiency, a certain enzyme deficiency that can cause rapid damage to your red blood cells, leading to anemia).
- In infants under the age of 3 months.
- If you have previously had a lung or liver reaction or peripheral neuropathy (tingling, numbness, or weakness in the limbs) after using nitrofurantoin or another antibiotic belonging to the nitrofuran group, consult your doctor. If you have any doubts about any of the above conditions, consult your doctor.

When should you be extra cautious with this medication?

Contact your doctor, pharmacist, or nurse before using this medication.

Contact your doctor if you experience fatigue, yellowing of the skin or eyes, itching, rash, joint pain, abdominal pain, nausea, vomiting, loss of appetite, dark urine, and pale or gray-colored stools. These may be symptoms of a liver disorder.

During long-term treatment, especially in older individuals, regular monitoring by the doctor is necessary to detect any potential side effects in a timely manner.

In some individuals with a dark skin color of African or Mediterranean descent, anemia may occur during treatment. If you belong to this group and experience fatigue, dizziness, and shortness of breath during treatment, stop taking the medication 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 medication and contact your doctor. The likelihood of these side effects increases, for example, if your kidneys are not functioning properly, if you have diabetes or anemia, or if you have a disease that causes severe weakness, or if you have had previous allergic reactions; inform your doctor about these conditions.

Complications in the lungs or liver may occur, as listed under "Possible side effects." If such complications occur, the use of this medication should be immediately discontinued.

Are you taking any other medications?

If you are taking other medications in addition to Nitrofurantoin, have taken them recently, or are likely to take other medications in the near future, inform your doctor or pharmacist.

Some of these medications may alter the effect of Nitrofurantoin:

- Antacids for indigestion (e.g., magnesium trisilicate)
- Medications for gout (e.g., probenecid or sulfinpyrazone)
- Medications that slow down the passage of food through the stomach (e.g., atropine, hyoscine)
- Medications for high pressure in the eye (glaucoma), such as carbonic anhydrase inhibitors (e.g., acetazolamide)
- Medications that make urine less acidic (e.g., potassium citrate mixture)
- Medications for infections known as quinolones
- The vaccine against typhoid fever, administered for typhoid prevention.

If you have any doubts about any of these medications, consult your doctor or pharmacist. Nitrofurantoin may affect the results of certain tests used to determine glucose in the urine.

What should you pay attention to regarding food and drink?

It is recommended to always take the capsules with food or a dairy product. This will help prevent stomach discomfort and facilitate absorption.

Pregnancy and breastfeeding.

Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Then contact your doctor or pharmacist before using this medication.

Pregnancy

As far as is known, this medication can be used during pregnancy. However, this medication should not be used just before and during childbirth, as it may have adverse effects on the baby.

Breastfeeding

If you plan to breastfeed, consult your doctor before using this medication.

Driving and using machinery

This medication can cause dizziness and drowsiness. If you experience these symptoms, do not drive or operate machinery until the symptoms have disappeared.

How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct usage, contact your doctor or pharmacist.

The capsules should be taken orally: take them during or shortly after a meal with a large amount of water (half a glass) or take them with some milk or yogurt. This ensures good tolerability and optimal results.

The recommended dosage is as follows:

Acute urinary tract infections: For adults and children aged 12 years and older: 1 capsule of 50 mg, 4 times a day (1 capsule with or shortly after each meal and 1 before bedtime). Usually for 5 to 7 days or at least 3 days after no infection is detectable in the urine.

For girls aged 5 to 12 years: 3-6 mg/kg body weight per day, divided into 4 doses, for 7 days or at least 3 days after no infection is detectable in the urine.

For short-term prevention during urinary tract surgeries and insertion of bladder catheters: For adults and children aged 12 years and older: 4 x 50 mg per day on the day of the procedure and for 3 days thereafter.

For long-term treatment of urinary tract infections: For adults and children aged 12 years and older: 1 capsule of 50 or 100 mg per day, usually in the evening before bedtime and after the last urination, for a maximum of 6 months.

When treatment is initiated, symptoms usually improve rapidly, usually within 1-3 days. Eventually, they disappear completely. However, it is important to complete the full course of treatment. Although the symptoms may have disappeared, it does not mean that all bacteria have been eradicated. If you stop the treatment too early, the symptoms may quickly return, which is unpleasant and medically undesirable. If the discomfort does not disappear or is significantly reduced after 3 days, consult your doctor again.

What should you do if you have taken too much of this medicine?

If too many capsules are taken at once, symptoms such as stomach irritation, nausea, and vomiting may occur. If you suspect an overdose, immediately contact a doctor. Your doctor will advise whether vomiting should be induced or if promoting excretion through urine by drinking plenty of fluids is necessary. Your doctor may also monitor blood counts, lung function, and liver function.

Have you forgotten to take this medication?

If you have forgotten to take a dose, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and continue with the regular dosing schedule. If you have missed multiple doses in a row, contact your doctor. They will likely prescribe another course of treatment for you.

If you stop taking this medication?

Even if you start feeling better, it is important to finish the entire prescribed amount of capsules for the number of days instructed by your doctor.

Never adjust the dosage on your own or stop the treatment without consulting your doctor, even if you experience unwanted side effects. First, discuss it with your doctor. They can advise you on whether you can stop and the best way to do so.

If you have any other questions about the use of this medication, please contact your doctor or pharmacist.

Possible side effects

Like any medication, this medication can have side effects. Not everyone experiences them.

All medications can cause allergic reactions, although severe allergic reactions are rare. If you experience sudden shortness of breath, difficulty breathing, swelling of the eyelids, face, or lips, skin rash, or itching (especially affecting your whole body), stop taking this medication and seek immediate medical attention. If you experience any of the side effects listed below, stop taking this medication and consult your doctor.

Sometimes this medication can cause the urine to become dark yellow to brown. This is a normal occurrence that will disappear on its own after completing the course of treatment.

If you notice any of the following side effects, immediately consult your doctor:

Your lungs may react to the use of this medication. This can happen quickly, within a week of starting the treatment, or very slowly, especially in elderly individuals. This can lead to fever, chills, cough, and shortness of breath associated with pneumonia and tissue damage.

This medication can cause liver inflammation, resulting in jaundice (yellowing of the skin or whites of the eyes).

Rarely (affects less than 1 in 1000 people):

Some patients may experience blood cell disorders, leading to bruising, delayed blood clotting, sore throat, fever, anemia, and susceptibility to cold or persistent colds.

- Various skin reactions have been reported, including skin peeling (flaking), red skin rash, or fever accompanied by rapid heartbeat and severe blistering rash.
- Other side effects may include:
- Feeling sick (nausea) and headache.
- Diarrhea.
- Loss of appetite, stomach pain, and vomiting.
- Dizziness and drowsiness.
- The nerves can be affected, resulting in changes in sensitivity and muscle function. Additionally, headaches, extreme changes in mood or mental state, confusion, weakness, and impaired vision may occur.
- Other reactions may include inflammation of the salivary glands (causing facial pain), inflammation of the pancreas (resulting in severe abdominal pain), and joint pain.
- Temporary hair loss.
- Inflammation of the blood vessel walls of small blood vessels, causing skin lesions, with unknown frequency.
- Increased pressure in the skull (causing severe headaches).
- Urinary tract infection caused by bacteria that are not sensitive to this medication.
- Severe allergic skin reactions (DRESS syndrome).
- Liver inflammation caused by the immune system attacking liver cells, with unknown frequency.
- Inflammation of kidney tissue surrounding tubules, leading to kidney failure, with unknown frequency.

If you experience a significant side effect or a side effect that is not listed in this leaflet, please contact your doctor or pharmacist.

How to store this medicine?

- Store below 25°C.
- Store in the original package to protect from moisture.
- Keep out of sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the box, blister, or label after "Exp." The expiry date refers to the last day of that month.
- Do not dispose of medications in wastewater or household waste. Ask your pharmacist how to dispose of medications that are no longer needed. These measures will help to protect the environment.