

Stop taking FURANTIL® if you experience conditions below and inform your physician or apply to the emergency department of the nearest hospital IMMEDIATELY:

- Sudden wheezing, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially in entire body)
 - FURANTIL® may affect your lungs in a short period such as a week, or very slowly in elderly patients. This condition may cause fever, chills, coughing and shortness of breath
 - Jaundice (yellowness on skin and sclera because of liver dysfunction)
 - Nerves out of spinal cord may be damaged, leading alterations in sense of touch and muscle use. In addition to this, headache, extreme alterations in mood, confusion, weakness and blurred vision may occur. These effects may be severe and sometimes irreversible (nonhealing).
 - Increasing of intracranial pressure (thus, severe headache)
- All of these are very serious side effects.
If you have one of these, you may need emergency medical intervention or be hospitalized.
The color of your urine may change to yellow or brown after using FURANTIL®. This is completely normal and there is no need to quit the treatment.

If you recognize any of the below, tell your physician:

- Nausea and headache
- Diarrhea
- Anorexia, stomachache and vomiting
- Dizziness, drowsiness
- Blood cells are affected in some patients, and because of this there may be some bruises, delays in blood clotting, sore throat, fever, anemia and sensitiveness to common cold or prolonged common cold can be observed.
- Various skin eruptions or reactions were seen in some patients. This condition manifests itself as flaking of the skin, fever and pain accompanied by red rash or tachycardia, and vesicular rash. Other reactions include inflammation of salivary glands (causing facial pain) and pancreatic gland (severe abdominal pain) and arthralgia.
- Short-term hair loss.
- Urinary tract infection caused by microbes not sensitive to FURANTIL®

If you encounter any side effect that is not included in this patient information leaflet, inform your physician or pharmacist.

5. How to store FURANTIL®?

Keep FURANTIL® out of the sight and reach of children and in its package.

Keep at room temperature under 25°C, away from light.

Use in line with expiry date.

Do not use FURANTIL® after the expiry date on the package and blister.

Product License Holder:

BIOACTIVE T, UNITED KINGDOM

BioActive T

FURANTIL® 50 mg CAPSULE

It is taken orally.

Each capsule contains:

- **Drug substance:** 50 mg nitrofurantoin.
- **Excipients:** Starch, talc (E553b), magnesium stearate (E572), croscarmellose sodium, titanium dioxide (E171), tartrazine FD&C yellow no:5 (E102), indigo carmine FD&C blue no:2 (E132), gelatin (E441).

Please read this PATIENT INFORMATION LEAFLET before you start to use the medicine, since it contains information that is important for you.

- Keep this patient information leaflet. You may need to read it later.
- If you have additional questions, please consult your physician or pharmacist.
- This medicine is prescribed for you personally, do not give it to others.
- During the use of this medicine, tell your physician that you are using this medicine when you apply to a doctor or a hospital.
- Please comply with the information in this patient information leaflet exactly. Do not use higher or lower dose of the medicine than the one recommended to you.

In This Patient Information Leaflet:

1. What is FURANTIL® and what it is used for?
2. Things to take into consideration before using FURANTIL®?
3. How to use FURANTIL®?
4. What are possible side effects?
5. How to store FURANTIL®?

Topics are included.

1. What is FURANTIL® and what it is used for?

FURANTIL® capsule is light-dark green and contains yellow homogeneous powder. It is presented in

30-capsule packagings, each capsule contains 50 mg of nitrofurantoin. Nitrofurantoin is an antibiotic and it is used in the prevention and treatment of the infections in the bladder and the other parts of the urinary tract.

2. Things to take into consideration before using FURANTIL®? DO NOT USE FURANTIL® in following situations

- If you are allergic (itching, redness on skin or difficulty in breathing) to nitrofurantoin or any of the excipients,
- If you have a kidney disease that affect the function of the kidneys severely (if you are not sure, please consult to your physician),
- If you are in the last month of your pregnancy or having labor pains since the medication has risks on the infant,

USE FURANTIL® CAUTIOUSLY in following situations

- If you have diabetes,
- If you have a condition that causes severe weakness,

- If you have anemia (pale skin, weakness and breath shortness because of the decrease in the red blood cell count), vitamin B deficiency or abnormal levels of salt in your blood,
- If you have allergic reactions in your history.

The conditions above may increase the possibility of a side effect that causes alterations and numbness in sense of touch because of nerve damage.

• In case of glucose-6-phosphate dehydrogenase enzyme (a chemical substance of the body) deficiency, this condition makes your red blood cells to be more easily-damaged (This deficiency is more common in Mediterranean, Middle Eastern, Asian and black people).

• If you have problems about your lungs, liver or nervous system, (If you need to use FURANTIL® for a couple of months, your physician may want to check your lungs and liver functions regularly.)

"If these cautions apply to you, even for any previous period, please consult to your physician."

Taking FURANTIL® with food and drink

Take FURANTIL® with food or milk. Taking the medicine with food or milk prevents the stomach problems, and also helps the absorption of the medicine.

Pregnancy

Please consult to your physician or pharmacist before using the medicine.

FURANTIL® can be used in pregnancy as far as we know. However using this medicine in the last month of your pregnancy, or if you are having labor pain, or during labor may affect the infant, therefore do not use this medicine in this period.

If you realize you are pregnant during the treatment, please consult to your physician or pharmacist immediately.

Lactation

Please consult to your physician or pharmacist before using the medicine.

Ability to drive and use machines

FURANTIL® may cause dizziness and drowsiness. If you are affected in this way, please do not drive and use machines until the symptoms in question are not observed.

Important information about some of the excipients in FURANTIL®
This medicinal product contains less than 1 mmol (23 mg) of sodium in each capsule; basically in other words it is "sodium-free".

Using with other medications

- Antacid for dyspepsia (e.g. magnesium tricyclate)
 - Medicines used in gout treatment (e.g. probenecid or sulfinpyrazole)
 - Medicines that slows down progress of food through stomach (e.g. atropine, hyoscine)
 - Medicines used for high intraocular pressure (glaucoma) such as carbonic anhydrase inhibitors (e.g. acetazolamide)
 - Medicines decreasing the acidity of urine (e.g. potassium citrate mixture)
 - Medicines used in infection treatment (e.g. quinolons)
- FURANTIL® may affect the results of some of the test that detects glucosuria.
- If you are using a prescribed or unprescribed medicine currently, or have used recently, please inform your physician or doctor about these.

3. How to use FURANTIL®?

Instructions for proper use and dose/dosing intervals:

Take FURANTIL® with food or milk, taking the medicine this way decreases the irritation in gastro-intestinal tract.
Your physician will inform you about the proper dose and dosing intervals according to the type of the disease.
Unless your physician advises otherwise, follow the instructions below.

Adults:

- In infection treatment: 50 mg or 100 mg capsule 4 times a day for 7 days.
- Superinfection prophylaxis: 50 mg of 100 mg capsule, one before bed.
- Infection prophylaxis during surgical procedures: 4 times a day, one 50 mg capsule on the day of the surgery and during the 3 days after the surgery.

Administration route and method:

It is taken orally.

Take the whole capsule with a sufficient amount of liquid (e.g., a glass of water or milk)

Various age groups:

Pediatric use:

Children and infants older than 3 months:
The dose is adjusted according to the weight of the child, and this dose is determined by the physician.
Follow your physician's instructions exactly.
FURANTIL® should not be used in infants younger than 3 months.

Geriatric use:

The same dose that applies for a normal adult should be used in elderly people on the condition that there is no significant kidney dysfunction.

Special administration conditions:

Renal failure:

FURANTIL® should not be used in the patients with impaired kidney function. The lowest dose which is effective, should be used in long-term, suppressor treatment.

Liver failure:

No data available.

If you have the impression that the effect of FURANTIL® is either very potent or very weak, please talk to your physician or pharmacist.

If you used more FURANTIL® than you should:

If you used more FURANTIL® than you should, please talk to a physician or pharmacist.

If you forget to use FURANTIL®

Do not worry if you forget to take your medicine. If you realize that you did not take your medicine on the same day, continue normal dosing. If you forget to take for a day, take at normal dose on the next day.

Do not take double doses to make up the missed dose.

The possible effects after ending the treatment with FURANTIL®

Your physician will inform you about the treatment period. Please do not quit the treatment before the specified time even if you feel well.

4. What are the possible side effects?

As with all medicines, there may be side effects in the individuals who are sensitive to any of ingredients of FURANTIL®. Most of them are mild and go away when you quit the treatment.