

• Increase in intracranial pressure (thus, severe headache)
All of these are very serious side effects.
If you experience any of these, you may need an emergency intervention or to be hospitalized.
After use of FURANTIL, your urine may become yellow or brown. This is quite normal and does not necessitate cessation of the drug.

If you notice any of the following please tell your doctor:

- Nausea and headache
 - Diarrhea
 - Loss of appetite, abdominal pain and vomiting
 - Dizziness, somnolence
 - In some patients, the blood cells are affected and thus bruising, late clotting of blood, sore throat, fever, anemia and vulnerability to cold or long-term cold may occur.
 - In some of the patients various rashes or skin reactions have occurred. This may come through peeling of the skin, red rashes or severe, vesicular skin rash associated with fever, pain and tachycardia. Other reactions include inflammation of salivary glands (which causes facial pain) and pancreatic gland (serious abdominal pain) and arthralgia.
 - Short-term alopecia
 - Urinary tract infection due to microorganisms insensitive to FURANTIL.
- These are minor side effects of FURANTIL.
If you notice any side effects not listed in this guide, please inform your doctor or pharmacist.

5. How to store FURANTIL

Keep FURANTIL out of reach and sight of children and in its packaging.
Store at room temperature, below 25°C, protected from light.

Use this medicine in accordance with its expiration date.

Do not use FURANTIL after the expiration date listed on the packaging and blister.

This guide has been approved on 01/08/2011.

DIRECTIONS FOR USE

FURANTIL 100 mg tablet

For oral use.

Each tablet contains;

- **Active Ingredient:** 100 mg nitrofurantoin,
- **Excipients** Lactose monohydrate, povidone K30, crospovidone, sodium starch glycolate, anhydrous colloidal silica, magnesium stearate (E572).

Before you start using this medicine, please read the DIRECTIONS FOR USE carefully, because it contains important information for your health.

- Keep this guide. You may need to read it again.
- If you have further questions, consult your doctor or pharmacist.
- This medicine has been prescribed for you; don't pass it on to others.
- If you go to a doctor or a hospital while using this medicine, tell them you are using it.
- Please follow the instructions written in this guide strictly. Use the exact dose that has been prescribed to you, do not use a higher or a lower dose.

In the Instructions for Use:

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

These headings are available.

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

FURANTIL tablet is yellow, round, bisect on one side and convex. It is presented in packaging of 30 tablets that contains 100 mg of nitrofurantoin in each tablet. Nitrofurantoin is an antibiotic and used for prevention and treatment of infections that occur in bladder as well as other parts of urinary tract.

2. Things to consider before using FURANTIL DO NOT USE FURANTIL if any of the following applies

- If you are allergic (itching, erythema or shortness of breath) to nitrofurantoin or any of the excipients,
- If you experience renal impairment that seriously affects renal functions (if you are not sure of this please consult to your doctor),
- Since the medication may have effects on your baby, if you are at the last month of your pregnancy or experiencing labor pains,

In the following situations, TAKE FURANTIL WITH SPECIAL CARE

- If you are diabetic,
 - If you have a disease that causes serious weakness,
 - If you have anaemia (pale skin, weakness and shortness of breath due to reduction in red blood cell count), Vitamin B deficiency or abnormal level of salt in your blood,
 - If you have an allergic reaction history,
- Above mentioned conditions may increase the probability of side effects that may lead to changes in sense of touch and numbness due to neural damage.
- If you have glucose-6-phosphat dehydrogenase enzyme (a chemical substance of body) deficiency, thus red blood cells are easily damaged (this

deficiency is more common in people from Mediterranean, Middle East, Asian and black people)

- If you have problems related with lungs, liver or nervous system, (if you need to use FURANTIL for a few months, your doctor may want to continuously control how your lungs and liver work)

"Please consult your doctor if any of these warnings applies to you even though it may have been anytime in the past."

Using FURANTIL with food and beverages

Take FURANTIL with food or milk. Taking medication together with food or milk prevents gastric disturbances, in addition helps absorption of the drug.

Pregnancy

Consult your doctor or pharmacist before using this medicine. As far as known, FURANTIL may be used during pregnancy. But, if you are at the last month of your pregnancy, it should not be taken at this stage of pregnancy since its use during labor pain and labor may affect the baby. If you find out you are pregnant during your treatment please consult your doctor or pharmacist immediately.

Lactation

Consult your doctor or pharmacist before using this medicine.

Driving or operating machinery

FURANTIL may cause dizziness and somnolence. If you are affected, you shouldn't drive or operate machines until aforementioned signs are not observed.

Important information on some of the excipients of FURANTIL

FURANTIL contains a sugar called lactose. If you are told by a doctor that you are intolerant to some of the sugars, please contact your doctor before using this medication. This medication contains less than 1 mmol (23 g) of sodium in each tablet; namely "it actually does not contain sodium".

Using FURANTIL with other medicines

- Antacids for dyspepsia (e.g.; magnesium trisilicate)
 - Drugs used for gout treatment (e.g.; probenecide or sulphydrylpyrazone)
 - Drugs that slow the passage of food through stomach (e.g.; atropine, hyoscine)
 - Drugs, such as carbonic anhydrase inhibitors, used in case intraocular pressure increases (glaucoma) (e.g.; acetazolamide)
 - Drugs that reduces the acidity of urine (e.g.; potassium citrate mixture)
 - Drugs used for treatment of infections (e.g.; quinolones) FURANTIL may effect the results of some of the tests for glycosuria.
- FURANTIL may affect the results of some of the tests for glycosuria. If you are taking or have recently taken any medicine with or without a prescription please tell your doctor or pharmacist about those medicines.

3. How to use FURANTIL?

Instructions for proper usage and dosage/frequency of application:

Take FURANTIL with food or milk. Using the medication in this way reduces the irritation in gastrointestinal tract.

Your doctor will inform you about the dose and dosing intervals which are appropriate for type of the disease.

Please follow the below mentioned instructions unless advised differently by your doctor.

Adults

- For infection treatment: One tablet of 50 mg or 100 mg 4 times daily for 7 days
- Prevention of additional infections: One 50 mg or 100 mg tablet before sleep.
- Prevention of infections during surgical operations: One 50 mg tablet 4 times a day on the operation day as well as for 3 days after operation.

Application procedure and method:

For oral use.

Take tablets as a whole with adequate amount of liquid (e.g.; a glass of water or milk).

Different age groups:

Use in Children:

Children and babies older than 3 months:

Dose is adjusted to the weight of the child and this dose is determined by the doctor. Please strictly follow your doctor's instructions.

FURANTIL shouldn't be administered to babies younger than 3 months.

Use in elderly people:

Elderly people should use the same dose for adults unless there is a significant renal impairment.

Use in specific situations:

Renal deficiency:

Patients with impaired renal function shouldn't use FURANTIL.

The minimum dose that may be effective for long-term, suppressive therapy should be used.

Hepatic deficiency:

No data is available.

If you have an impression about the effect of FURANTIL being too strong or weak, please talk to your doctor or pharmacist. If you have used more FURANTIL than you should If you have used more FURANTIL than you should talk to a doctor or a pharmacist. If you forget to use FURANTIL Don't worry if you've forgotten to take your medication. If you realize at the same day that you haven't taken your medication, then continue with normal dosing. If you've forgotten to take for a day, then take it with normal dosing next day. Do not take a double dose to make up for the dose you have forgotten. Effects that may occur after stopping the treatment with FURANTIL Your doctor will tell you how long the treatment will last. Even if you feel good, please do not stop using the drug before the time mentioned.

4. What are possible side effects?

Like all medicines, FURANTIL can cause side effects for people who are sensitive to its ingredients. Most of them are mild and disappear after cessation of the drug.

If you experience any of the following, stop using FURANTIL and IMMEDIATELY talk to your doctor or go to the emergency room of the closest hospital.

- Sudden wheezing, shortness in breath, swelling, rash itching in facial area or around lips (particularly at the whole body)
- FURANTIL may have an impact on your lungs as a short time as a week or may have a very slow effect particularly in elderly patient. This may cause fever, chill, cough and shortness in breath.
- Hepatitis (yellowing of the sclera and skin due to hepatic impairment).
- Nerves outside the spinal cord may be affected, thus this may cause changes in sense of touch and use of muscles. In addition to this, headache, great changes in mood, confusion, weakness, and blurry vision may occur. These effects may be severe and sometimes permanent (non-healing).