Package leaflet: information for the user

FURAMAG 25 mg Hard Capsules
FURAMAG 50 mg Hard Capsules

Furaginum solubile

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.

In this leaflet:

1. What Furamag is and what it is used for

Active substance of medicine Furamag furagin soluble is an antibacterial of nitrofuran group. It is used in the treatment of urinary tract infectious diseases caused by microorganisms susceptible to furagin soluble (cystitis, urethritis, pyelonephritis); prostatitis, gynecological infections.
For prophylaxis it may be used in cases of urological surgery, cystoscopy, catheterisation and also for prophylaxis of urinary tract infections relapse.

2. What you need to know before you take Furamag

Do not take Furamag
- if you are hypersensitive to furagin soluble, nitrofuran derivatives or any of the other ingredients of this medicine (listed in section 6.)
- if you have severe renal impairment
- if you have polyneuropathy (including diabetic)
- if you have porphyria
- if you are pregnant
- if you are breast-feeding

Warnings and precautions
Talk to your doctor or pharmacist before taking Furamag:

- if you have deficiency of glucose-6-phosphate dehydrogenase (the risk of development of hemolysis is possible)
- if you have kidney function disturbances. Furamag is not recommended in case of infection of kidneys parenchyma.
- if you have anemia
- if you have deficiency of vitamin B group and folic acid
- if you have pulmonary diseases
- if you have diabetes (this medicine can cause development of polyneuropathy)
- if you have or had inclination to allergy

Tell your doctor if you have any of mentioned indications.

Prolonged use of Furamag
- can cause development of peripheral neuropathy (pain, sensitivity disorders in the area of the appropriate nerve). In these cases the use of the drug should be discontinued and you should consult your doctor.
- the doctor may indicate you to control the functions of kidneys and liver, as well as lungs functions, especially in patients over 65 years of age (due to pulmonary fibrosis risk).
- in case of prolonged use of Furamag prophylactic doses, clinically significant microorganisms' resistance is not formed.

There are no reports of pseudomembranous colitis treatment with Furamag, although reports of pseudomembranous colitis has nearly all antibacterial agents, including nitrofuran derivatives. Should be taken into account the possibility of these adverse reactions in patients who experienced diarrhea during the use of antimicrobials due to rectal natural microflora inhibition. Unlike antibiotics, Furamag insignificantly changes the gut microflora. In case of mild case of pseudomembranous colitis, antibacterial agent discontinuation is sufficient.
Patients, who use Furamag can give false positive results for presence of glucose in the urine if copper reduction method is used for the determination of glucose. If enzyme method is used to determine glucose quantity in the urine, Furamag does not affect the results.

Other medicines and Furamag
Tell your doctor if you are taking, have recently taken or might take any other medicines.

The preparation is not recommended to take concomitantly with sulphanilamides, because this combination can negatively affect haemapoiesis. When the preparation is used concomitantly with antibiotics penicillin and cephalosporin, its antibacterial activity is significantly enhanced. Furamag performs well combined with tetracyclines and erythromycin.

The agents that alkalify the urine decrease nitrofurane activity. The agents that acidify the urine (acids including ascorbic acid as well as calcium chloride) increase effect of Furamag, but may increase risk of toxic effects.

The concomitant use with quinolones (nalidixic acid, norfloxacin, oxolinic acid) should be avoid. When Furamag is used concomitantly with uricosurics (*Probenicid, Sulfinpyrazon*), a toxic effect may increase.

Furamag with food, drink and alcohol
Food promotes the medicine absorption. Alcoholic beverages must be avoided during the treatment period as the concomitant use of alcohol and furagin soluble may cause unfavorable side effects.

Pregnancy and breast-feeding
Taking of Furamag is contraindicated.

Driving and using machines
Furamag has no effect on the ability to drive and use machines.

3. How to take Furamag

Always take Furamag exactly as your doctor has told you. You should check with your doctor if you are not sure.
Capsule is used orally after meals, should be swallowed unbroken with plenty of liquid.

– **Furamag 50 mg hard capsules**

Treatment. *Adults* are indicated 50 mg to 100 mg 3 times daily.

Use in children and adolescents
Children with body weight over 30 kg – 50 mg 3 times daily.
Treatment course is 7 to 10 days. If necessary, the course may be repeated after 10 to 15 days.
Prophylaxis. *Adults and children with body weight over 30 kg* – 50 mg before bedtime.

– **Furamag 25 mg hard capsules**

Treatment. *Adults* are indicated 50 mg to 100 mg 3 times daily.

Use in children and adolescents
The recommended dose for children weighing over 30 kg is 50 mg 3 times daily.
The recommended dose for children 1 to 10 years of age is 5 mg/kg body weight per day; the daily dose should be divided into 2 to 3 doses. If the daily dose cannot be divided equally, the largest portion of the dose should be taken at bedtime.

Children		Daily dose	
age	body weight	mg	number of 25 mg hard capsules
1 to 1,5 years of age	10-13	50-65	2-3
1.5 to 2 years of age	14-15	70-75	3
3 to 4 years of age	16-18	80-90	3-4
5 to 6 years of age	19-24	95-120	4-5
7 to 10 years of age	25-30	125-150	5-6

Duration of the treatment should be 7 - 10 days. If necessary, the treatment course can be repeated in 10-15 days.

Prophylaxis
The recommended dose for children 1 to 10 years of age is 1-2 mg/kg body weight per day before bedtime 3-6 months in case of chronic cystitis or until prevention of the obstruction in case of pyelonephritis.

Special populations
Furamag should be used with caution *in patients with impaired hepatic function*, the monitoring of hepatic function during treatment is advised.
Furamag should be used with caution *in patients with impaired renal function*, the monitoring of renal function during treatment is advised.
Furamag should be used with caution *in elderly patients*.

If you take more Furamag than you should
In case of suspected overdose, immediately call your doctor. Take into consideration the symptoms indicated in the section *Side effects*.

If you forget to take Furamag
If you forget to take a regular dose, take the next dose at the ordinary time.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Furamag
Do not stop the treatment without consulting a doctor. If you stop the treatment before the end of the prescribed course of the treatment, the desirable therapeutic effect will not be achieved.
If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, Furamag can cause side effects, although not everybody gets them.
Side effects frequency convention:
Very common – 1 or more often than 1 patient of 10
Common – less often than 1 of 10, but more often than 1 of 100 patients
Uncommon - less often than 1 of 100, but more often than 1 of 1000 patients
Rare - less often than 1 of 1000, but more often than 1 of 10 000 patients
Very rare - less often than 1 of 10 000 patients, including isolated reports

Common:
- headache.

Uncommon:
- dizziness, drowsiness;
- nausea, flatulence (side effects can be minimized by using the medicine with food).

Rare:
- peripheral neuropathy;
- visual impairment;
- vomiting, loss of appetite, diarrhea, dyspepsia, constipation, abdominal pain (side effects can be minimized by using the medicine with food);
- papular rash, itching.

Very rare:
- disorders of haemopoesis: (agranulocytosis, trombocytopenia, aplastic anemia);
- acute or chronic pulmonary reactions. Acute pulmonary reaction develops rapidly. It manifests itself as severe shortness of breath, fever, chest pain, cough with or without sputum, eosinophylia. Simultaneously with acute pulmonary reactions urticaria, itching, nettle-rash, angioedema, and myalgia have been reported. Acute pulmonary reactions are based on a hypersensitivity reaction that can occur within several hours, rare – in minutes. Acute lung reaction is reversible, it disappears after drug discontinuation. Chronic pulmonary reaction may occur after interruption of a longer period of treatment using nitrofurans. It is characterised by a gradual worsening of shortness of breath, fast breathing, unstable fever, eosinophylia, progressive cough and interstitial pneumonitis and/or pulmonary fibrosis;
- pancreatitis (side effects can be minimized by using the medicine with food);

- angioedema, urticaria, exfoliative dermatitis, *Erythema multiforme*, reversible alopecia;
- arthralgia;
- mild intracranial hypertension;
- increased body temperature, fatigue;
- cholestatic jaundice, hepatitis.

To reduce the side effects the drug is recommended for administration with sufficient amount of water, vitamins B group and antihistamines.
The urine may be coloured dark yellow or brown using *Furamag.*
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Furamag

Do not store above 25°C. Store in original package in order to protect from light and moisture.
Keep out of the sight and reach of children.
Do not use Furamag after the expiry date which is stated on the package after ''EXP''. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Furamag contains
The active substance is furagin soluble (Furaginum solubile).
Each *Furamag 25 mg* hard capsule contains 25 mg of furagin soluble.
Each *Furamag 50 mg* hard capsule contains 50 mg of furagin soluble.
The other ingredients are potassium carbonate, magnesium carbonate and talc.

What Furamag looks like and contents of the pack
Furamag 25 mg hard capsules
Hard gelatine capsules of brownish-yellow colour containing orange-brown to reddish-brown powder. The presence of white, yellow, orange or orange-brown particles is allowed.
Capsule content: gelatine, colouring agent – Titanium dioxide E171, Yellow iron oxide E 172.

Furamag 50 mg hard capsules
Hard gelatine capsules of yellow colour containing orange-brown to reddish-brown powder.
The presence of white, yellow, orange or orange-brown particles is allowed.
Capsule content: gelatine, colouring agent – Titanium dioxide E171, Quinoline yellow E104.

Package: 10 hard capsules in blister, 3 blisters (30 hard capsules) with patient leaflet in the carton box.

Marketing Authorisation Holder and Manufacturer
JSC Olainfarm.
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