

Package leaflet: Information for the user

Furosemide Pinewood 40 mg Tablets furosemide

Read all of this leaflet carefully before you start using 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Furosemide Pinewood 40 mg Tablets are and what they are used for
2. What you need to know before you take Furosemide Pinewood 40 mg Tablets
3. How to take Furosemide Pinewood 40 mg Tablets
4. Possible side effects
5. How to store Furosemide Pinewood 40 mg Tablets
6. Contents of the pack and other information

1. What Furosemide Pinewood 40 mg Tablets are and what they are used for

What Furosemide Pinewood 40 mg Tablets are

The name of your medicine is Furosemide Pinewood 40mg Tablets (called Furosemide Pinewood 40 mg Tablets throughout this leaflet). Furosemide Pinewood 40 mg Tablets contain a medicine called furosemide. Furosemide Pinewood 40 mg Tablets belong to a group of medicines called diuretics (water tablets).

What Furosemide Pinewood 40 mg Tablets are used for

Furosemide Pinewood 40 mg Tablets can be used to help you lose extra water in your body very quickly. It is given when you have a lot of extra water in your body. Furosemide Pinewood 40 mg Tablets are often used when you have too much water around your heart, lungs, liver or kidneys.

How Furosemide Pinewood 40 mg Tablets work

Furosemide Pinewood 40 mg Tablets work by helping you to pass more water (urine) than you usually do. If the extra water in your body is not removed, it can put extra strain on the heart, blood vessels, lungs, kidneys or liver.

2. What you need to know before you take Furosemide Pinewood 40 mg Tablets

Do not take Furosemide Pinewood 40 mg Tablets if:

- You are allergic (hypersensitive) to furosemide or any of the other ingredients of Furosemide Pinewood 40 mg Tablets (listed in Section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You are allergic to sulphonamides such as sulfadiazine or co-trimoxazole
- You have been told by a doctor that you have kidney failure. In some types of kidney failure, it is still okay to have this medicine. Your doctor will be able to decide
- You have severe liver problems
- Your doctor has told you that you have a low blood volume or are dehydrated
- You are not passing any water (urine)
- You have too little potassium or sodium in your blood (shown in blood tests)

- You are breast-feeding (see “Pregnancy and breast-feeding” section below)

Do not take Furosemide Pinewood 40 mg Tablets if any of the above apply to you. If you are not sure, talk to your doctor or nurse before taking Furosemide Pinewood 40 mg Tablets.

Warnings and precautions

Talk to your doctor or nurse before you take this medicine if:

- You have difficulty in passing water (urine)
- You are 65 years of age or older
- You are taking an antipsychotic drug called risperidone
- You have low levels of protein in your blood (hypoproteinemia). This will show in blood tests.
- You suffer from acute porphyria symptoms of which may include severe stomach, back or thigh pain. Nausea, vomiting or constipation may also present along with weakness in arms and legs.
- You have liver or kidney problems
- You have diabetes
- You have low blood pressure or feel dizzy when you stand up
- You have prostate problems
- You have gout
- You feel dizzy or dehydrated. This can happen if you have lost a lot of water through being sick, having diarrhoea or passing water very often. It can also happen if you are having trouble drinking or eating
- You are going to have a glucose test
- If the person having the medicine is a premature infant. This is due to the possible formation of kidney stones

If you have systemic lupus erythematosus (SLE) - a disease of the immune system which affects skin, bones, joints and internal organs.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before taking Furosemide Pinewood 40 mg Tablets.

Other medicines and Furosemide Pinewood 40 mg Tablets

Please tell your doctor or nurse if you are taking or have recently taken any other medicines.

This includes medicines you buy without a prescription, including herbal medicines.

This is because Furosemide Pinewood 40 mg Tablets can affect the way some other medicines work.

Also, some medicines can affect the way Furosemide Pinewood 40 mg Tablets work. In particular, tell your doctor if you are taking any of the following:

The following medicines can affect the way Furosemide Pinewood 40 mg Tablets work and increase the chance of you getting side effects:

- Medicines such as ramipril, enalapril, perindopril (called ‘ACE inhibitors’) or losartan, candesartan, irbesartan (called ‘angiotensin II receptor antagonists’). Your doctor may need to change the dose of your tablets or ask you to stop taking them
- Medicines for high blood pressure or heart problems. Your doctor may need to change the dose of your medicine
- Medicines to help you sleep and relax such as chloral hydrate
- Medicines used as a general anaesthetic for relaxing your muscles during surgery
- Medicines for diabetes. These may not work as well when you are using Furosemide Pinewood 40 mg Tablets
- Theophylline – used for wheezing or difficulty in breathing
- Phenytoin – used for epilepsy. This can lower the effect of Furosemide Pinewood 40 mg Tablets

- Risperidone – an antipsychotic drug.

The following medicines can increase the chance of side effects when taken with Furosemide Pinewood 40 mg Tablets:

- Lithium – used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood
- Cisplatin – used for some cancers
- Digoxin – used for heart problems. Your doctor may need to change the dose of your medicine
- Non-steroidal anti-inflammatory drugs (NSAIDs) – used for pain and inflammation such as aspirin, ibuprofen, ketoprofen or indomethacin
- Carbamazepine – used for epilepsy
- Aminoglutethimide – used for breast cancer
- Ciclosporin – used to stop the rejection of organs after a transplant
- Methotrexate – used for cancers of the skin, joint or bowel diseases
- Carbenoxolone and sucalfate – used for ulcers of the foodpipe (gullet)
- Reboxetine – used for depression
- Amphotericin – used for fungal infections if used for a long time
- Corticosteroids – used for inflammation (such as prednisolone)
- Liquorice – often used in cough medicines if taken in large amounts
- Probenecid (used with another HIV medicine)
- Medicines for infection such as gentamicin, amikacin, neomycin, netilmicin, tobramycin, vancomycin or high doses of cephalosporins
- Medicines used before X-ray examinations (radiocontrast agents)
- Medicines used for constipation (laxatives) if used for a long time such as bisacodyl or senna
- Medicines for asthma when given in high doses such as salbutamol, terbutaline sulphate, salmeterol, formoterol or bambuterol
- Other water tablets (diuretics) such as bendroflumethiazide and metolazone. Your doctor may need to change the dose of your medicine

Pregnancy, breast-feeding and fertility

Do not take Furosemide Pinewood 40 mg Tablets if you are pregnant. Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you might be pregnant. Do not breast-feed if you are taking Furosemide Pinewood 40 mg Tablets. This is because small amounts may pass into the mother's milk. Talk to your doctor before taking this medicine if you are breast-feeding or planning to breast-feed. Ask your doctor or nurse for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may feel dizzy or unwell after taking Furosemide Pinewood 40 mg Tablets. If this happens, do not drive or use any tools or machines.

Furosemide Pinewood 40 mg Tablets contains Lactose

This medicine contains 0.105 g lactose per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

3. How to take Furosemide Pinewood 40 mg Tablets

Follow your doctors direction about when and how to take your medicine and look at the label. Your

pharmacist may also help if you are not sure.

How much Furosemide Pinewood 40 mg Tablets is given

Adults:

The recommended starting dose is 40 mg (1 tablet) of furosemide once a day or on alternate days. Your doctor may adjust your dose gradually until you respond. You should NOT adjust the dose unless instructed to do so by your doctor.

In very serious cases your doctor may ask you to take up to a maximum 1,500 mg per day.

Elderly:

Your doctor may start you on a lower dose and gradually increase this dose.

Use in children

For children the dose depends on the weight of the child (1-3 mg/kg body weight daily) with a maximum dose of 1 tablet daily. Ask your doctor for advice.

Unless your doctor has told you differently take your tablets in the morning. Swallow them with a glass of water.

If you take more Furosemide Pinewood 40 mg Tablets than you should

If you take more Furosemide Pinewood 40 mg Tablets than you should contact your doctor immediately or consult with your nearest hospital casualty department. Taking too much Furosemide Pinewood 40 mg Tablets may make you feel confused, unable to focus, show a lack emotion or interest in anything. You may also have dizziness, light headedness, fainting (due to low blood pressure), uneven heartbeat, muscle weakness or cramps and blood clots (signs include pain and swelling at the part of body that is affected). You may also have problems with your kidneys or blood.

If you forget to take Furosemide Pinewood 40 mg Tablets

If you miss a dose, take it as soon as you remember unless it is nearly time for your next dose. Never double-up on the next dose to make up for the one missed.

If you stop taking Furosemide Pinewood 40 mg Tablets

Keep taking Furosemide Pinewood 40 mg Tablets until your doctor tells you to stop.

Blood tests

Your doctor may carry out blood tests to check that the levels of some salts in the blood are at the correct levels.

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

4. Possible side effects

Like all medicines, Furosemide Pinewood 40 mg Tablets can cause side effects, although not everybody gets them.

Tell your doctor or nurse straight away if you notice any of the following serious side effects – you may need urgent medical treatment

- If you have an allergic reaction. The signs may include a rash, joint pain, fever (systemic lupus erythematosus), inflammation of the kidney (nephritis), swollen ankles or high blood pressure, skin rashes, change in skin colour, severe blistering of the skin, being more sensitive to the sun than usual, high temperature (fever), and itching
- You bruise more easily, get more infections, feel weak or tired more than usual. Furosemide Pinewood 40 mg Tablets can affect the number of blood cells, causing serious blood problems.

Very common (affects more than 1 in 10 people):

- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint

pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can lead to blood clots or 'gout'.

Common (affects less than 1 in 10 people):

- You notice yellowing of your skin or eyes and your urine becomes darker in colour. These could be signs of a liver problem. In patients who already have liver problems, a more serious liver problem known as liver encephalopathy may occur. Symptoms include forgetfulness, fits, mood changes and coma.

Rare (affects less than 1 in 1,000 people):

- Severe allergic reactions. The signs may include shock such as difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat
- Inflammation of your blood vessels (vasculitis). Symptoms may include fever, loss of appetite, weight loss, aches and pains.

Very rare (affects less than 1 in 10,000 people):

- Severe stomach or back pain. These could be signs of 'pancreatitis'.

Frequency unknown:

- You find it hard to urinate. This could be a symptom of acute urinary retention.
- You suffer from a kidney disorder where there is an increased amount of calcium in your kidneys. This could be a symptom of nephrocalcinosis.
- You suffer from blood in your urine or pain in your abdomen or groin. This could be a sign of kidney stones (nephrolithiasis).
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome. In a more severe form of the condition called Toxic Epidermal Necrolysis, layers of the skin may peel off to leave large areas of raw exposed skin all over the body.
- You have blood clots.

Tell your doctor as soon as possible if you have any of the following side effects:

Very common (affects more than 1 in 10 people):

- Headaches, feeling dizzy or light-headed when standing up quickly. Also loss of concentration, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood pressure
- Change in the amount of some salts (such as calcium, potassium, magnesium, sodium and chloride) which are needed for your body to work properly. Signs include increased thirst, headaches, low blood pressure, confusion, muscle cramps, muscle weakness, fast or irregular heart rate and stomach upset.

Uncommon (affects less than 1 in 100 people):

- Problems hearing
- Deafness.

Rare (affects less than 1 in 1,000 people):

- Tingling or feeling numb on the skin.

Very rare (affects less than 1 in 10,000 people):

- Ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys
- Reduction in blood cells which can cause bruising, make infections more likely, make skin pale

yellow or cause weakness or breathlessness (anaemia).

Frequency unknown:

- Change in the levels of some salts (such as sodium or chloride) in the urine.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

Common (affects less than 1 in 10 people):

- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine.

Uncommon (affects less than 1 in 100 people):

- Feeling sick (nausea) or a general feeling of being unwell
- If you have diabetes you may be less able to control the levels of glucose in your blood.

Rare (affects less than 1 in 1,000 people):

- Diarrhoea and being sick (vomiting).

Very rare (affects less than 1 in 10,000 people):

- An illness where the removal of bile from the liver is blocked (intrahepatic cholestasis). Signs include jaundice, rash or fever and the colour of your water (urine) becomes darker.

Frequency unknown:

- People with bladder and prostate problems may notice pain when passing water. This is due to an increase in the amount of water passed.

Blood tests

Furosemide Pinewood 40 mg Tablets can change the levels of liver enzymes or body fats known as cholesterol and triglycerides.

A blood test may show changes in the way the kidneys are working, indicating a significant reduction in kidney function.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below.

Ireland

HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemide Pinewood 40 mg Tablets

This medicinal product does not require any special storage conditions.

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

Do not throw away medicines 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 pack and other information

What Furosemide Pinewood 40 mg Tablets contains

The active substance in this medicine is furosemide. Each tablet contains 40 mg of furosemide. The other ingredients are lactose monohydrate, maize starch, pregelatinized starch, sodium starch glycollate (type A) and magnesium stearate.

What Furosemide Pinewood 40 mg Tablets looks like and contents of the pack

The tablets are white or off white, circular tablets, marked F on one side (F & 40 separated by breakline) & plain on other side and are available in carton packs of 50, 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pinewood Laboratories Ltd.,
Ballymacarbry,
Clonmel,
Co. Tipperary,
Ireland

Manufacturer

Flavine Pharma France,
3, Voie d'Allemagne,
13127 Vitrolles,
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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Furosemide Pinewood 40 mg Tablets

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