

Patient Information Leaflet

Furosemide 40mg Tablets

Read all of this leaflet carefully before you start taking this medicine.
Keep this leaflet. You may need to read it again.
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 have any further questions, ask your doctor or pharmacist.
If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT FUROSEMIDE 40MG TABLETS ARE AND WHAT THEY ARE USED FOR

Furosemide belongs to group of medicines called “diuretics”. Diuretics make you pass more water (urine).

Excess fluid can build up in certain conditions which affect the heart, lungs, kidneys or liver. Furosemide 40mg Tablets are used to remove that fluid by making you pass more water. They may also be used when your kidneys are not functioning properly and not producing normal amounts of urine, or to treat high blood pressure, alone or in combination with other medicines.

2. BEFORE YOU TAKE FUROSEMIDE 40MG TABLETS

You should not take Furosemide 40mg Tablets if:

- You know that you have an allergy to furosemide or any of the other ingredients (see section 6 of this leaflet)
- You know you are allergic to the antibiotics known as sulphonamides, e.g. trimethoprim, sulfadiazine
- You have very low levels of potassium, sodium or other electrolytes in your blood (your doctor will be able to advise you)
- You have severe kidney damage which has stopped them functioning and producing urine
- You have a severe liver disease (cirrhosis)
- You have a blood disorder called porphyria which can affect the skin and nervous system
- You are suffering from digitalis toxicity (harmful effects of the drug digoxin).

Speak to your doctor if one of these applies to you before you are given this medicine.

Before you take Furosemide 40mg Tablets:

Your doctor will take special care if any of the following situations apply to you. Make sure your doctor is aware of these situations, if it is not already obvious:

- You have difficulty in passing water, for example because of an enlarged prostate gland (males only)
- You have been told that you have a low volume of fluid in the body or a low blood pressure
- You have diabetes or any disease of the adrenal glands
- You have any problems with your liver or kidneys
- You have gout (causes excess uric acid in the blood and painful inflammation of the joints, mainly in the feet and hands and especially in the big toe).

Taking other medicines:

Tell your doctor before you are given this medicine if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, including herbal medicines.

This is because Furosemide tablets can affect the way some other medicines work. Also some medicines can affect the way Furosemide tablets work.

Do not take these medicines, and tell your doctor, if you are taking:

- Medicines which change the amount of potassium in your blood. These include potassium supplements such as potassium chloride or certain water tablets (diuretics) such as triamterene.
- The following medicines can affect the way Furosemide 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. If you are going to have anaesthetic please ensure that the doctor or nurse knows you are taking furosemide.

- Medicines for diabetes- These may not work as well when you are taking Furosemide Tablets
- Theophylline- used for wheezing or difficulty in breathing
- Phenytoin- used for epilepsy. This can lower the effect of Furosemide Tablets
- Risperidone- an antipsychotic drug

The following medicines can increase the chance of side effects when taken with Furosemide Tablets

- Lithium- used for mental illness. 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.
- Medicines used for the treatment of irregularity of the heart (arrhythmias) like amiodarone, disopyramide, flecainide and sotalol.
- 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 (redness and swelling) such as aspirin, ibuprofen, ketoprofen or indometacin.
- Carbamazepine-used of epilepsy.
- Aminoglutethimide- used for breast cancer
- Ciclosporin - used to stop the rejection of organ after a transplant.
- Methotrexate - used for cancers of the skin or some joint or bowel diseases.
- Carbenoxolone and Sucralfate- used for ulcers of the food pipe (digestive tract).
- Reboxetine- used for depression.
- Amphotericin- used for fungal infections, if used for a long time.
- Corticosteroids- used for inflammation or allergy such as prednisolone.
- Liquorice- often used in cough medicines if taken in large amounts.
- Probenecid
- Medicines for infection such as gentamicin, amikacin, neomycin, netilmicin, tobramycin, vancomycin or high doses of cephalosporins.
- Medicines used for injections before X-ray examinations (radiocontrast agent).
- 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. Your doctor may need to change the dose of your medicine.

Pregnancy and breast feeding:

Do not take Furosemide 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 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.

Driving and using machines:

Furosemide may cause some patients to be less alert which could interfere with the ability to drive or to operate machines. If you notice that you are not as alert as usual, do not drive or operate machinery and ask your doctor for advice.

Important information about some of the ingredients of Furosemide 40mg Tablets:

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

3. HOW TO TAKE FUROSEMIDE 40MG TABLETS

Furosemide 40mg Tablets are to be taken by mouth.

Your doctor will decide on the most suitable dose for you, and how the medicine will be given. The dosage and frequency of repeated doses may change depending on how you respond to treatment. Do not change without first checking with your doctor.

Adults: The initial dose is 40mg a day, reduced to 20mg daily or 40mg on alternate days, depending on how you respond.

Elderly: Furosemide is generally cleared from the body more slowly in the elderly. If you are elderly, your doctor may decide to start with a low dose and increase the dose gradually according to your response.

Children: The doctor will decide on the dosage, depending on how severely the kidneys are affected and on the response to initial doses.

Whilst you are receiving treatment with this medicine, your doctor may want to take blood for testing which will show if you have the right balance of fluid and chemicals in the body.

Your doctor will tell you how long your treatment with Furosemide 40mg Tablets will last. If you think that the effect of your tablets is too strong or too weak, or if you have any further questions on the use of this product, ask your doctor or pharmacist.

If you think you have taken more Furosemide 40mg Tablets than you should have:

If you think that you, or any other person, have taken too many tablets, contact your doctor or hospital casualty department immediately. Take any remaining tablets and this leaflet with you so that the medical staff know exactly what you have taken.

If you forget to take your Furosemide 40mg Tablets:

If you miss a dose, wait until your next dose. Do not take the dose you have missed.

You can then carry on as before. Do not take more than one dose at a time.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Furosemide 40mg Tablets can sometimes cause side-effects, although not everyone gets them.

If any of the below mentioned side effects are observed please inform your doctor immediately

- allergic reactions such as itching, skin rash with severe itching and nettle rash, fever, allergic to light, severe allergic reaction with (high) fever, red patches on the skin, joint pain and/or inflammation of the eyes, severe, acute (allergic) reaction accompanied by fever and blisters on the skin/peeling skin and tiny spots from bleeding in the skin.
- sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen, shifting towards the back.

The other possible side effects are listed under headings of frequency, using the following categories:

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

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

Common

Furosemide can cause an excessive depletion of bodily fluids (e.g. passing urine more often than normal) and minerals (sodium, potassium, magnesium, calcium). Symptoms that can occur are thirst, headache, confusion, muscle cramps, increased irritability of the muscles, muscular weakness, heart rhythm disturbances and gastrointestinal problems such as sensation of unease and discomfort in stomach with an urge to vomit, or diarrhoea.

If you have a shortage of sodium (sodium deficiency):

- cramp in the calf muscles
- loss of appetite
- listlessness
- feeling of weakness
- dizziness
- drowsiness
- confusion.

If you have a shortage of potassium (potassium deficiency):

- muscular weakness and the inability to contract one or more muscles (paralysis)
- increased excretion of urine
- heart problems
- in the case of severe potassium deficiency: interference with the function of the intestine or confusion, which can result in coma.

If you have a shortage of magnesium and calcium (magnesium and calcium deficiency):

- increased irritability of the muscles
- heart rhythm disturbances.
- Lowering of blood pressure, resulting in impaired concentration and reactions, light-headedness, a feeling of pressure in the head, headache, dizziness, drowsiness, a feeling of weakness, visual disturbances, dry mouth and an inability to stand upright.

Uncommon

- abnormal blood count accompanied by bruising and a tendency to bleed
- sensitivity to light (photosensitivity).
- involuntary leakage of urine
- in the elderly, this can lead to a low blood volume, fluid depletion and thickening of the blood. This can cause clots to form in the blood.

Rare

- abnormal blood count (white blood cell deficiency) accompanied by a increased susceptibility to infection
- increase in certain substances (eosinophilic cells) in the blood
- a crawling sensation on the skin, itching or tingling without any reason
- a life-threatening form of unconsciousness
- hearing disorders & ringing in the ears. These disorders are usually temporary in nature
- inflammation of a blood vessel
- acute kidney failure
- inflammation of the kidneys associated with blood in the urine, fever and pain in the sides

If you have a urinary tract obstruction, increased urine production may occur or worsen.

- if you have a bladder disorder, enlarged prostate or narrowing of the ureters, urine production can stop suddenly
- shock (severe drop in blood pressure, extreme paleness, restlessness, weak fast pulse, clammy skin, impaired consciousness) as a result of a sudden severe dilatation of the blood vessels due to allergy to certain substances
- fever
- minor mental disturbances

Very rare

- anaemia (a condition characterised by shortage of red blood cells)
- very severe blood abnormality (white blood cell deficiency) accompanied by a sudden high fever, severe throat pain and ulcers in the mouth
- certain liver function disorders
- increase in certain liver enzymes.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FUROSEMIDE 40MG TABLETS

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

Do not use this medicine after the expiry date printed on the container. The expiry date refers to the last day of the month.

Do not store above 25°C. Protect from light.

6. FURTHER INFORMATION

The active substance is furosemide.

The other ingredients are lactose, starch, magnesium stearate, povidone, sodium starch glycollate.

What Furosemide 40mg Tablets looks like and contents of pack:

Each tablet contains 40mg of furosemide.

The tablets are packed in plastic child proof containers of 100, 250, 500 or 1000 tablets. The tablets are also packed in blisters of 28 tablets. Not all pack sizes may be marketed

Marketing authorisation holder:

Mercury Pharma (Generics) Ltd, No. 1 Croydon, 12-16 Addiscombe Road, Croydon CR0 0XT, UK.

Manufacturer

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