Package leaflet: Information for the user

Furosemide 20 mg tablets

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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Furosemide is and what it is used for
2. What you need to know before you take Furosemide
3. How to take Furosemide
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1. What Furosemide is and what it is used for

Furosemide belongs to a group of medicines called diuretics (water tablets).
Your doctor has prescribed furosemide to treat a condition called oedema where there is too much water in your body. This could be due to problems with your heart, lungs, kidneys, liver, blood vessels or high blood pressure. Furosemide helps your kidneys to get rid of the extra water that is not needed in your body.

2. What you need to know before you take Furosemide

Do not take Furosemide if you:
- are allergic to furosemide, other sulphonamide related medicines or any of the other ingredients of this medicine (listed in section 6)
- have anuria (failure of the kidneys to produce urine) or impaired kidney function or kidney failure resulting from poisoning by nephrotoxic and/or hepatotoxic agents
- have severe kidney damage which has stopped them from working properly and producing urine
- have very low levels of potassium, sodium or other electrolytes in your blood or low blood volume (your doctor will be able to advise you)
- are dehydrated
- have low blood pressure
- take potassium supplements or potassium sparing diuretics for high blood pressure (e.g. amiloride or spironolactone)
- have liver cirrhosis (the symptoms are tiredness, weakness, water retention, feeling or being sick, loss of weight or appetite, yellowing skin or eyes, itch) or liver encephalopathy, condition in which toxic substances accumulate in the blood (the symptoms are confusion, altered levels of consciousness and coma as a result of liver failure)
- have Addison's disease (low levels of corticosteroid hormones secreted)

- have digitalis poisoning (feeling or being sick, high levels of potassium in the blood, slow, fast or irregular heartbeats)
- are breast-feeding.

Warnings and precautions
Check with your doctor or pharmacist before taking Furosemide if you:
- have low blood volume (hypovolaemia) or are at risk of developing low blood pressure
- have low levels of protein in the blood (hypoproteinaemia) as a result of kidney damage
- have liver congestion (slowed blood flow through the vessels) or other liver problems
- have kidney problems
- have or may have diabetes. If you are taking insulin, your doctor may need to adjust your insulin dosage
- if you are elderly, if you are on other medications which can cause the drop of blood pressure and if you have other medical conditions that are risks for the drop of blood pressure
- have prostate trouble or difficulty passing urine
- have or have had gout
- have an abnormal blood condition
- are about to undergo any blood or urine tests.

Your doctor will want to monitor you and may take blood for testing while you are taking this medicine.

Other medicines and Furosemide
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. Especially:
- medicines used to treat high blood pressure known as angiotensin converting enzyme (ACE) inhibitors or Angiotensin-II receptor antagonists, such as captopril, losartan
- medicines used to treat high blood pressure or prostate problems known as alpha-blockers, such as prazosin
- medicines used to treat high blood pressure, angina (type of chest pain) and heart failure known as beta blockers, such as propranolol, atenolol, sotalol
- medicines used to treat high blood pressure and other medicines used to remove water from the body known as diuretics, such as acetazolamide and metolazone
- medicine used to treat heart failure and unusual heart rhythms, called digoxin
- medicines used to treat unusual heart beats, such as amiodarone, disopyramide, flecainide, lidocaine and mexiletine
- a medicine used to prevent atrial fibrillation (disease of the heart characterized by irregular heartbeat), medicine used to prevent clotting and stroke called warfarin
- a medicine used to treat high cholesterol, called clofibrate
- medicines used to treat pain and inflammation
- known as nonsteroidal anti-inflammatory drugs (NSAIDs), such as indometacin or salicylates such as aspirin
- medicines used to treat inflammation known as corticosteroids, such as prednisolone and dexamethasone
- medicines used to treat infections caused by bacteria, such as lymecycline, vancomycin, gentamicin, ceftriaxone and colistin
- medicines used to treat infections caused by fungus, such as amphotericin
- medicines used to treat infections caused by a virus, such as nelfinavir, ritonavir and saquinavir
- medicine used to prevent rejection after transplants, such as tacrolimus, ciclosporin
- medicines used to treat depression, such as reboxetine, amitriptyline and phenelzine
- medicines used to treat mental problems called ‘psychoses’, such as risperidone, amisulpride, sertindole, pimozide and chlorpromazine
- a medicine used to treat extreme mood swings, called lithium

- a medicine used to treat Attention Deficit Hyperactivity Disorder (ADHD), called atomoxetine
- medicines used to treat epilepsy, such as carbamazepine, phenobarbital and phenytoin
- medicines to treat asthma, such as salmeterol, salbutamol and theophylline. These medicines also treat chronic obstructive pulmonary disease
- medicines used to treat blocked noses, such as ephedrine and xylometazoline
- a medicine used to treat mouth ulcers and problems with the digestive area of the stomach (the upper gastrointestinal area), called carbenoxolone
- medicines used to treat cancer, called cisplatin and methotrexate
- medicine used to treat constipation, such as laxatives
- a medicine used to treat gout, called probenecid
- potassium salts used to treat low potassium in the blood
- anything that contains large amount of liquorice
- a medicine used to treat stomach ulcers, called sucralfate. Do not take sucralfate within two hours of taking furosemide. This is because the sucralfate can stop the furosemide from working properly
- medicines used as injections before X-ray examinations (radiocontrast agent).

Your doctor may need to change your dose and/or to take other precautions if you are taking one of the following medicines:

- Aliskiren – used to treat high blood pressure

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking furosemide.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
Do not drive or operate machinery if you feel less alert after taking Furosemide.

Furosemide 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.

Sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'

3. How to take Furosemide

Always take this medicine exactly as your doctor or pharmacist has told you. If you are not sure, check with your doctor or pharmacist.

Swallow the tablets with a glass of water.

The recommended dose is:
Adults, children over 12 years and adolescents:

- Water retention: the usual starting dose is 2 tablets (2 x 20 mg) in the morning, 1 tablet (20 mg) a day or 2 tablets (2 x 20 mg) on alternate days. Do not exceed 4 tablets (4 x 20 mg) a day.
- High blood pressure: the usual dose is 1-2 tablets (20-40 mg) twice a day.

Elderly: If you are elderly, your doctor may tell you to take a lower dose.
Children under 12 years: a more suitable dosage form is used in this age group.

Dosage adjustment may be necessary in patients with:
• hypoproteinaemia (low level of protein in the blood)
• liver congestion/dysfunction.

If you take more Furosemide than you should
If you take more medicine than your doctor has told you to, contact a doctor or your nearest hospital immediately and take your Furosemide with you. Symptoms of an overdose include dehydration and changes in the levels of certain chemicals in the blood.

If you forget to take Furosemide
If you forget to take a dose, take another as soon as you remember. Then take your next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Furosemide
Speak to your doctor before you stop taking Furosemide

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you have any of the following side effects while taking this medicine **tell your doctor immediately or go to the hospital straight away:**
- Severe allergic reaction which may include a skin rash, itching, dermatitis, peeling skin, sensitivity to sunlight or sun lamps or fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever could be signs of a condition called Stevens-Johnson syndrome
- Inflammation of blood vessels (vasculitis, which may cause rash, fever and joint or muscle pains) or kidney inflammation, this may change the number of times you pass urine or you may see blood in your urine. You may have a fever, feel drowsy, or notice swelling e.g. of the ankles
- Blood clot (causing pain, swelling or tenderness in the legs).

Tell your doctor or pharmacist if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people):
- Dehydration, altered balance of fluid or chemicals in the body (e.g. sodium, potassium, chlorine, calcium and magnesium) causing a dry mouth, weakness, tiredness or drowsiness, restlessness, fits, muscle pain, fatigue or cramps, low blood pressure causing loss of concentration and slowed reactions, difficulty passing water, fast or irregular heart rate and feeling and being sick.

Common (may affect up to 1 in 10 people):
- Low blood volume (hypovolaemia)
- Increased creatinine and blood urea (seen in blood tests).

Uncommon (may affect up to 1 in 100 people):
- Anaemia causing tiredness, breathlessness, unusual bleeding or bruising
- Changes in the body seen in tests such as levels of cholesterol, glucose, uric acid
- Gout
- Changes in vision including blurred or yellow vision
- Light-headedness, sensations of pressure in the head, headache, drowsiness, weakness, dizziness when standing
- Irregular heartbeat
- Muscle cramps or weakness

- Changes in the amount or need to urinate
- Tiredness
- Dry mouth, thirst, feeling or being sick, changes in bowel movements including diarrhoea and constipation
- Deafness (sometimes irreversible).

Rare (may affect up to 1 in 1,000 people):
- Changes in blood cells such as amount of white blood cells, reduction of platelets causing a rash fever, sweating, tiredness, and weight loss. Your doctor will perform regular blood tests to ensure no changes have occurred.
- Psychiatric disorder NOC causing delusions, hallucinations, disorganized speech
- Feeling 'pins and needles' or tingling sensation
- Confusion, headache, tiredness, generally feeling unwell, fever
- 'Ringing' in the ears, loss of hearing usually reversible
- Symptoms of shock such as changes in heart rate, breathlessness, cool clammy skin
- Inflammation of the pancreas causing pains in your abdomen or back and nausea
- Changes in the liver causing yellowing of the skin or whites of the eyes
- Skin rashes.

Very rare (may affect up to 1 in 10,000 people):
- Involuntary movements of the muscle
- Inflammation or failure of the kidney which may cause back pain or changes in the amount or need to urinate.

Not known (frequency cannot be estimated from the available data):
- Worsening of conditions where there is already balances of fluid or chemicals in the body
- Acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- Decreased levels of potassium in the body.

Additional side effects in children
- Increased risk or persistence of patent ductus arteriosus (problem in the structure of the heart that is present at birth) in premature infants
- Kidney stones in infants.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Furosemide

Keep this medicine out of sight and reach of children.

Store in the original package in order to protect from light. This medicinal product does not require any special temperature storage conditions.

Do not use this medicine after the expiry date stated on the carton. 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 to protect the environment.

6. Contents of the pack and other information

What Furosemide contains

• The active substance is furosemide. Each tablet contains 20 mg of furosemide.
• The other ingredients are: lactose monohydrate, magnesium stearate, maize starch, pregelatinised starch, sodium starch glycolate (Type A).

What Furosemide looks like and contents of the pack

Furosemide 20 mg tablets: White to off white, round tablets (6.00 mm ± 0.2mm) marked F on one side & plain on the other side 20

Furosemide 20 mg tablets are supplied in white opaque PVDC coated PVC/Aluminium blisters of 10 and 14 tablets.
Pack size: 28, 30, 50, 56, 84, 90, 98, 100 tablets.

Not all pack sizes may be marketed.

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