

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Furosemide 20mg and 40mg 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. 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.

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
4. Possible side effects
5. How to store Furosemide
6. Contents of the pack and other information

1 What Furosemide is and what it is used for

Furosemide belongs to a group of medicines called diuretics (also called water tablets). It works by interfering with the filtration process of the kidneys to reduce the amount of sodium and water taken back into the blood stream, thus increasing the volume of urine produced.

Furosemide is used to treat oedema (fluid retention) caused by heart failure, certain liver and kidney disorders, blood vessels or high blood pressure.

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 (listed in section 6)
- have severe kidney damage which has stopped them 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 (tiredness, weakness, water retention, feeling or being sick, loss of weight or appetite, yellowing skin or eyes, itch) or liver encephalopathy (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 heartbeat)
- are breast-feeding

Warnings and precautions

Talk to your doctor 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
- may have diabetes. If you are taking insulin, your doctor may need to adjust your insulin dosage
- are elderly
- are on other medications which can cause a drop in blood pressure and if you have other medical conditions that are a risk for a drop in blood pressure
- have prostate trouble or difficulty passing urine
- 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 those obtained without a prescription. This includes herbal medicines.

Medicines which may interact with or be affected by Furosemide

- medicines to lower blood pressure, such as ACE inhibitors, renin inhibitors, alpha blockers, calcium channel blockers, diuretics, phenothiazines
- medicines to treat mental illness (e.g. pimozide, amisulpride, sertindole)
- medicines for arrhythmias (e.g. sotalol, amiodarone, flecainide)
- digoxin for your heart
- moxislyte for Raynaud's syndrome
- nitrates (for angina)
- lithium for depression or mania
- sucralfate for stomach ulcers. Leave 2 hours apart
- cholestyramine or colestipol for high cholesterol. Leave 2 hours apart
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) e.g. ibuprofen, naproxen, aspirin
- antibiotics for infections that affect your kidneys or ears (e.g. cefaclor, colistin, gentamicin, vancomycin)
- amphotericin (to treat fungal infections)
- chloral hydrate (to treat insomnia)
- antidepressants (e.g. monoamine oxidase inhibitors (MAOIs))
- medicines to control diabetes such as insulin or tablets
- antiepileptics e.g. phenytoin or carbamazepine
- corticosteroids or antihistamines (to treat allergic reactions)
- medicines for ADHD
- medicines treating cancer e.g. aldesleukin
- levodopa (for parkinson's disease)
- oral contraceptives
- alprostadil for erectile dysfunction
- certain treatments for asthma such as theophylline or salbutamol
- probenecid to prevent gout
- laxatives used over a long period of time
- medicines or food containing liquorice
- if you are about to undergo a procedure where curariform muscle relaxants (e.g. vecuronium) or anaesthetics may be used, tell your anaesthetist/dentist or healthcare professional

Furosemide and alcohol

You should avoid drinking alcohol while taking Furosemide tablets as this may lower your blood pressure further.

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.

Furosemide contains sodium

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

3 How to take Furosemide Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablet should be swallowed whole with a glass of water.

Doses:

- **Adults and children over 12 years:**
Water retention: the usual starting dose is 40mg in the morning, then 20mg a day or 40mg on alternate days. Up to 80mg a day may be given.
High blood pressure: 20-40mg twice a day.
- **Elderly:** may be reduced in this age group.
- **Children under 12 years:** 1-3mg per kg of bodyweight. A more suitable dosage form e.g. oral solution, may be appropriate.
- Dosage adjustment may be necessary in patients with: hypoproteinaemia, liver congestion/dysfunction

If you take more Furosemide than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you. **Symptoms of an overdose include:** dehydration, electrolyte depletion and low blood pressure.

If you forget to take Furosemide

Take it as soon as you remember, unless it is time for your next dose. If you miss a dose, do not take a double dose to make up for a forgotten dose.

If you stop taking Furosemide

Do not stop taking Furosemide without talking to your doctor.

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

4 Possible side effects

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

Seek medical advice immediately if you develop the following symptoms:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness (severe anaphylactic reactions including shock)
- Frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)
- Fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme)
- Severe blistering of the skin, mouth, eyes and genitals, (Stevens -Johnson syndrome)
- Small raised bumps on the skin that fill with fluid or pus caused by a hypersensitivity (allergy) to medicine (Acute Generalised Exanthematous Pustulosis (AGEP))
- Fever, general ill feeling, swollen/enlarged lymph nodes and skin eruption (Drug Rash with Eosinophilia and Systemic Symptoms) (DRESS)

Other side effects

Uncommon (may affect up to 1 in 100 people)

- A reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- Disrupted heart rhythm/irregular heartbeat
- Deafness (sometimes irreversible)
- Visual disturbances
- Tiredness
- Dry mouth, thirst
- Feeling sick (nausea) or being sick (vomiting)

- Changes in bowel movements including diarrhoea and constipation
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Increased creatinine and blood urea (detected in blood tests)

Rare (may affect up to 1 in 1,000 people)

- A reduction in white blood cells (leucopenia)
- Abnormal condition of the bone marrow in which it is unable to produce normal amounts of red blood cells, white blood cells, and platelets leaving the immune system in a weakened state and vulnerable to infection (bone marrow depression)
- Tingling or numbness in the hands or feet (paraesthesia)
- Hyperosmolar coma (a complication of type 2 diabetes involving extremely high blood sugar and dehydration causing unconsciousness)
- Hearing disorders and ringing in the ears (tinnitus)
- Fever
- Generally feeling unwell (malaise)
- Inflammation of blood vessels (vasculitis)
- Inflammation of the pancreas (pancreatitis)
- Skin rashes with the formation of wheals (urticaria)
- Peeling of the skin over large areas of the body (exfoliative dermatitis)
- Skin rash caused by small blood vessels bleeding into the skin (purpura)
- Inflammation of the kidney (interstitial nephritis), kidney failure
- Minor mental disturbances

Very rare (may affect up to 1 in 10,000 people)

- More prone to infections due to a severe reduction in number of white blood cells (agranulocytosis)
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia)
- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (haemolytic anaemia)

Not known (frequency cannot be estimated from the available data)

- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- Blistering of the skin (bullous pemphigoid)

Furosemide may also cause:

- A reduction in blood pressure
- A decrease in glucose tolerance
- A build-up of bile acids in the bloodstream causing persistent itch (cholestasis)
- An increase in liver enzymes (detected in blood tests)
- A disorder of the brain (encephalopathy) in patients with liver insufficiency
- Electrolytes (in particular, sodium, potassium, calcium and magnesium) and water balance disturbances
- Changes to blood cholesterol, triglyceride, creatinine and urea levels
- A decrease in blood volume as a result of blood/plasma loss and/or plasma fluid (hypovolaemia)
- Muscle spasm
- Increased urine production, urinary incontinence, urine retention
- An increased risk of a congenital heart defect (persistent patent ductus arteriosus) in premature infants given furosemide in the initial weeks after birth
- Calcium deposits in the kidney/kidney stones in premature infants.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 the sight and reach of children.
- Do not use this medicine 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 store above 25°C. Store in the original packaging.
- Medicines should not be disposed of 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:

Each tablet contains 20mg or 40mg of Furosemide.

The other ingredients are: lactose, magnesium stearate, sodium starch glycollate and maize starch.

What Furosemide Tablets looks like and contents of the pack:

- Furosemide 20mg tablets are white, circular, flat, bevelled-edge tablets marked with FIL/F20 on one side and plain on the other. Tablet diameter is 6mm.
- Furosemide 40mg tablets are white, circular, flat, bevelled-edge tablets marked with FIL/F40 on one side and plain on the other. Tablet diameter is 8mm.

Furosemide is available in:

Furosemide tablets are available in:

20mg: Container - 28, 56, 100, 250, 500 or 1000 tablets. Blister – 28 or 56 tablets.

40mg: Container - 28, 56, 100, 250, 500, 504, 1000 or 1008 tablets. Blister - 28, 56 or 1008 tablets.

Not all pack sizes or types may be marketed.

Product Licence Numbers:

- Furosemide 20mg Tablets: PL 11311/0710
- Furosemide 40mg Tablets: PL 11311/0711

Marketing Authorisation Holder:

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