

Furosemide 20 mg and 40 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 side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Furosemide Tablets are and what they are used for

The name of your medicine is Furosemide 20 mg and 40 mg Tablets (referred to as Furosemide Tablets in this leaflet). Furosemide Tablets contain the active ingredient furosemide which belongs to a group of medicines known as loop diuretics. Diuretics increase the amount of urine you produce by making your kidneys allow more water and salts to be removed from your body.

Furosemide Tablets are used to treat oedema which is a build up of fluid in the body tissues. The oedema can be caused by heart or kidney failure, liver damage or an obstruction. In some cases the fluid may build up in your legs and hands, and in other cases, in air spaces of your lungs (pulmonary oedema). Furosemide Tablets help your kidney to remove some of the excess fluid from your body.

Furosemide Tablets can also be used to treat mild to moderate high blood pressure, either on its own or in combination with other drugs.

2. What you need to know before you take Furosemide Tablets

Do not take Furosemide Tablets

- if you are allergic to furosemide or any other ingredients of this medicine (listed in section 6).
- if you have severe kidney damage which has stopped them working properly and producing urine
- if you 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)
- if you are dehydrated
- if you have low blood pressure
- if you take potassium supplements or potassium sparing diuretics for high blood pressure (e.g. amiloride or spironolactone)
- if you 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)
- if you have Addison's disease (low levels of corticosteroid hormones secreted)
- if you have digitalis poisoning (feeling or being sick, high levels of potassium in the blood, slow, fast or irregular heart beats)
- if you are breast-feeding

Warnings and precautions

Talk to your doctor or pharmacist before taking Furosemide Tablets

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

If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking.

If any of these apply to you, or if you are not sure, tell your doctor.

Other medicines and Furosemide Tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any medicines obtained without a prescription.

This is especially important if you are taking any of the following:

- medicines to lower your blood pressure, such as ACE inhibitors, renin-inhibitors, alpha blockers, calcium channel blockers, other diuretics and phenothiazines
- medicines to treat mental illness (e.g. pimozide, amisulpride, sertindole)
- medicines for arrhythmias (e.g. sotalol, amiodarone, flecainide, disopyramide)
- digoxin for your heart
- moxislyte for Raynaud's syndrome
- nitrates (for angina)
- lithium for depression or mania
- sucralfate for stomach ulcers
- colestyramine or colestipol for high cholesterol
- non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen or naproxen
- aspirin for pain
- 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)
- cytotoxics/platinum containing compounds
- drugs 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 foods 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

Laboratory Tests

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

Furosemide Tablets and alcohol

Alcohol should be avoided 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

This medicine can make you feel dizzy, less alert or cause blurred vision in rare cases. Do not drive or operate machinery if you are affected.

Furosemide Tablets contain lactose

Furosemide Tablets contain lactose. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking Furosemide Tablets.

3. How to take Furosemide Tablets

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

The breakline is not intended for breaking the tablet.

Recommended dose

Adults and children over 12 years

Oedema

The starting dose is 40 mg (one 40 mg tablet or two 20 mg tablets) a day. Then 20 mg a day or 40 mg on alternate days. Some patients may require a higher dose and may be told to take up to 80 mg (two 40 mg tablets or four 20 mg tablets) or more a day, given as two or more doses during the day.

High blood pressure

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

The usual daily dose for children is between 1 and 3 milligrams for each kilogram of body weight, up to a maximum total dose of 40 mg per day (i.e. two 20 mg tablets or one 40 mg tablet).

Dosage adjustment may be necessary in patients with:

- hypoproteinaemia
- liver congestion/dysfunction

If you take more Furosemide Tablets than you should

If you realize you have taken more Furosemide Tablets than your doctor has recommended (or if someone else has taken some of your Furosemide Tablets), contact your doctor right away. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

An overdose could cause dehydration, changes in the levels of certain chemicals in the blood and low blood pressure.

If you forget to take Furosemide Tablets

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for the forgotten dose.

If you stop taking Furosemide Tablets

Speak to your doctor before you stop taking Furosemide Tablets.

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 unwanted side effects, although not everybody gets them.

Severe side effects

If you notice any of the following, **stop taking** Furosemide Tablets and contact your doctor **immediately**:

- severe allergic reaction which may include a skin rash, itching, hives, dermatitis, peeling skin, sensitivity to sunlight or sun lamps or fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing
- 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)
- 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
- 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
- inflammation or failure of the kidney which may cause back pain or changes in the amount or need to urinate
- Acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- decreased levels of potassium in the body, with neuromuscular symptoms (muscular weakness, paralysis), intestinal symptoms (vomiting, constipation, meteorism), renal symptoms (polyuria) or cardiac symptoms. Severe potassium depletion can result in paralytic ileus or confusion, which can result in coma.

Other side effects

Other side effects of Furosemide Tablets include:

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, changes in vision, dry mouth, 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

- Psychiatric disorders for example causing delusions, hallucinations, disorganised speech
- Feeling 'pins and needles' or tingling sensation
- Confusion
- Headache
- 'Ringing' in the ears, loss of hearing usually reversible
- Skin rashes
- Tiredness, generally feeling unwell
- Fever
- Inflammation of blood vessels (vasculitis, which may cause rash, fever and joint or muscle pains)
- Shock, liver enzymes increased

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

- Involuntary movements of the muscle

Not known: frequency cannot be estimated from the available data

- Worsening of conditions where there are already imbalances of fluid or chemicals in the body
- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)

Additional side effects in children

- increased risk or persistence of patent ductus arteriosus 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

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

5. How to store Furosemide Tablets

Keep this medicine out of the sight and reach of children. Do not store above 25°C.

Containers: Keep the container tightly closed and store in the original container.

Blisters: Store in the original package.

Do not use this medicine after the expiry date that is stated on the carton, container or blister 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 Furosemide Tablets contain

Each Furosemide Tablet contains 20 mg or 40 mg of the active ingredient furosemide.

The other ingredients are lactose, maize starch, magnesium stearate, povidone and sodium starch glycolate.

What Furosemide Tablets look like and the contents of the pack

Furosemide 20 mg Tablets are white, circular, flat tablets with a breakline and F/20 embossed on one face.

Furosemide 40 mg Tablets are white, circular, flat tablets with a breakline and F/40 embossed on one face.

Furosemide 20 mg and 40 mg Tablets are available in blister packs of 28 and in container packs of 250 (20 mg) or 1000 (40 mg).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK.

Manufacturer

Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK.

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