

PACKAGE LEAFLET: INFORMATION FOR THE USER

Furosemide 20mg Tablets Furosemide 40mg Tablets (furosemide)

Read all of this leaflet carefully before you start taking this medicine.

- 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 or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

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

Furosemide Tablets contain furosemide as the active ingredient. This belongs to a group of medicines called diuretics (also called water tablets). Furosemide Tablets are used to treat oedema (fluid retention) caused by heart failure, mild to moderate hypertension (high blood pressure) and certain liver and kidney disorders. They are also used to manage a condition called oliguria where the body produces an abnormally small amount of urine, due to kidney disease.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FUROSEMIDE TABLETS

Do not take Furosemide Tablets if you:

- are allergic (hypersensitive) to furosemide, other sulphonamide related drugs (e.g. Sulphamethoxazole) or any of the other ingredients in Furosemide tablets (see 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 heart beats)
- are breast-feeding

Warning and precautions

Talk to your doctor or pharmacist or nurse before taking Furosemide Tablets

- if you suffer from low blood volume (hypovolaemia) or are at risk of developing low blood pressure
- if you suffer from low levels of protein in the blood (hypoproteinaemia) as a result of kidney damage
- if you suffer from gout or diabetes
- if you have kidney/adrenal or liver problems
- if you have a prostate problem or difficulty in passing urine
- if you are elderly
- increased risk of kidney problem in premature infants (deposition of calcium)

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

Other medicines and Furosemide Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking:

- medicines used to treat high blood pressure, such as ACE inhibitors (e.g.

- Enalapril), alpha blockers (e.g. Prazosin)
- antibiotics (e.g. Cefaloridine, Vancomycin)
- non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. Indometacin, Ketorolac)
- corticosteroids (e.g. Prednisolone)
- medicines used to treat diabetes (e.g. Insulin)
- salicylates (e.g. Aspirin)
- muscle relaxants (e.g. Vecuronium)
- antihistamines (e.g. Cetirizine)
- drugs used to treat arrhythmias (e.g. Sotalol, Amiodarone, Flecainide)
- drugs used to treat heart conditions (e.g. Digoxin, Tocainide)
- vasodilators (e.g. Hydralazine)
- renin inhibitors (e.g. Aliskiren)
- medicines used to treat angina (e.g. Nitrates)
- drugs to treat mental illness (e.g. Pimozide, Amisulpride)
- chelating agents (e.g. Sucralfate)
- cholesterol lowering agents (e.g. Cholestyramine, Colestipol)
- medicines used to treat depression (e.g. Lithium, Reboxetine)
- antiepileptics (e.g. Phenytoin, Carbamazepine)
- medicines used to treat fungal infections (e.g. Amphotericin)
- CNS stimulants and medicines for ADHD (e.g. Atomoxetine)
- immunomodulators (e.g. Aldesleukin)
- medicine used to treat erectile dysfunction in man (e.g. Alprostadil)
- certain treatments for asthma such as Theophylline or Salbutamol
- medicine used to treat gout (e.g. Probenecid)
- medicines used as a general anaesthetic for relaxing your muscles during surgery (e.g. Midazolam)
- laxatives used over a long period of time (e.g. Lactulose)
- medicines or foods containing liquorice

Furosemide tablets with food, drink 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 or pharmacist for advice before taking this medicine.

Furosemide Tablets should only be taken during pregnancy if considered essential by your doctor, and only for short-term treatment. Furosemide passes into breast milk, so inform your doctor if you are breast-feeding.

Driving and using machines

As this medicine may reduce mental alertness and cause dizziness, you should not drive or operate machinery until you know how the drug affects you.

Furosemide Tablets Contains Lactose - if you know you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.

For **Oral Use Only**.

Furosemide Tablets should be swallowed with a drink of water.

Adults: The usual initial dose is 40mg a day, reduced to 20mg daily or 40mg on alternate days. If you suffer from long term kidney trouble, your doctor may prescribe a starting dose of 250mg per day which may be increased by 250mg every 4 to 6 hours, up to a maximum dose of 1,500 mg per day.

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.

Use in children: The dose is worked out according to the child's weight. A dose of 1 - 3mg for each kilogram of the child's body weight should be given daily. Do not exceed 40mg per day.

If you take more Furosemide Tablets than you should

If you or anyone else has swallowed a lot of the tablets, contact your doctor or nearest hospital casualty department immediately.

If you forget to take Furosemide Tablets

If you miss a dose, take another as soon as you remember and carry on as before (do not take a double dose to make up for a forgotten dose). You should continue to take these tablets for as long as your doctor tells you to.

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, Furosemide Tablets can cause side effects, although not everyone gets them.

If you have any of the following side effects while taking your medicine tell your doctor immediately or go to 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
- 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)
- signs of Bone marrow suppression : sore throat, fever, mouth ulcers
- signs of low blood cell numbers for example unexplained bleeding and bruising, tiredness
- tinnitus (ringing in the ears)
- loss of hearing
- inflammation of the pancreas (pancreatitis) signs are pain in upper abdomen, feeling sick and vomiting
- serious skin reactions with peeling and blistering e.g Stevens Johnsons syndrome, Toxic epidermal necrolysis
- jaundice-yellowing of skin and eyes
- kidney problems and kidney failure

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, 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
- low blood pressure causing loss of concentration and slowed reactions, light-headedness, sensations of pressure in the head, headache, dizziness, 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

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, dizziness
- '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
- inflammation or failure of the kidney which may cause back pain or changes in the amount or need to urinate
- tiredness, generally feeling unwell
- fever

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 is already balances of fluid or chemicals in the body
- increased levels of glucose in the body

Additional side effects in children

- increased risk or persistence of patent ductus arteriosus in premature infants.
- kidney stones in premature babies

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.

Store in the original package/container and keep tightly closed.

This medicine should not be used after the expiry date printed on the pack.

Medicines should not be disposed of 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 Tablets contain

The active substance is furosemide, 20mg or 40mg.

The other ingredients are lactose, magnesium stearate (E572), sodium starch glycollate maize starch and starch paste 15% (see Section 2 'Important information about some of the ingredients of Furosemide Tablets').

What Furosemide Tablets look like and contents of the pack

20mg tablets - white circular flat bevelled edged tablet with 'F scoreline 20' embossed on one face and plain on the reverse.

40mg tablets - white circular flat bevelled edged tablet with 'F scoreline 40' embossed on one face and plain on the reverse.

Pack sizes (not all may be marketed):

20mg - 28, 56, 100, 250, 500, 1000 tablets.

40mg - 28, 56, 100, 250, 500, 504, 1000, 1008 tablets.

Marketing Authorisation Holder and Manufacturer

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