

## Package Leaflet: Information for the user

### Furosemide 20mg Tablets Furosemide 40mg Tablets

#### Furosemide

**Read all of this leaflet carefully before you start using 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

Furosemide is one of a group of medicines called diuretics ('water tablets'). Your doctor has prescribed Furosemide Tablets 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 is also used to treat high blood pressure.

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

##### Do not take Furosemide Tablets:

- if you are allergic to furosemide, other diuretics or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to sulphonamides (drugs used to treat infections, e.g. sulphamethoxazole)
- if you are dehydrated or have lost a lot of blood
- if you have kidney failure or you are not passing any urine
- if you have very low levels of potassium in your blood which will make your muscles feel weak or you may suffer paralysis
- if you have very low levels of sodium in your blood which may be caused by excessive sweating, vomiting or reaction to another drug
- if you are breast feeding
- if you have liver disease causing symptoms that affect your central nervous system such as changes in mood, confusion or drowsiness.

#### Warnings and precautions

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

- if you are pregnant or planning to become pregnant
- if you suffer from prostate trouble
- if you have difficulty in passing urine
- if you have diabetes
- if you have gout

- if you have low blood pressure or feel dizzy when you stand up
- if you suffer from porphyria (a genetic or inherited disorder of the red blood pigment haemoglobin). Symptoms include severe stomach, back or thigh pain. Nausea, vomiting or constipation may also be present along with muscle weakness in arms and legs
- if you have kidney problems as a result of liver disease
- if you are the parent or carer of a premature baby, as your doctor will need to monitor your child's kidney function. This is due to the possible formation of kidney stones
- if you are elderly, you may be more sensitive to the effects of furosemide tablets
- if you have ever suffered from cramps (electrolyte deficiency, salt imbalance)
- if you have low levels of protein in your blood (hypoproteinaemia). This will show in blood tests
- if you feel dizzy or dehydrated
- if you are going to have a glucose test
- if you are elderly, if you are on other medications which can cause the drop in blood pressure and if you have other medical conditions that are risks for the drop of blood pressure.
- if you have, or have ever had Systemic Lupus Erythematosus (SLE), a disease of the immune system which affects skin, bones, joints and internal organs.

**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.

- **Digoxin** used to treat heart failure or an irregular heartbeat; your doctor may need to change your dose.
- **Drugs to lower blood pressure** such as ACE inhibitors, beta-blockers, calcium channel blockers, alpha-blockers or vasodilators: when taken with furosemide may cause your blood pressure to fall too low or affect your heart. Your doctor may need to change your dose of furosemide.
- **Antibiotics** for infections such as cephalosporins: some antibiotics can affect your kidneys and furosemide can make this effect worse.
- **Carbenoxolone, liquorice and sucralfate** for stomach ulcers. Your salt balance may be altered causing your muscles to feel weak while taking carbenoxolone and liquorice. Do not take furosemide within two hours of taking sucralfate as furosemide will not work as well.
- **Lithium** for depression or mania: as the effect of lithium may be increased. Your doctor will check your lithium levels and may change your dose.
- **Aspirin and Indometacin** non steroidal anti-inflammatory medicines used to relieve pain and inflammation: Furosemide may increase the side effects of aspirin. Indometacin (used for treating rheumatism) can reduce the effect of furosemide.
- **Medicines to control diabetes or high blood pressure:** these medicines may not work as well when taken with furosemide.
- **Aminoglycosides e.g. gentamycin** for serious infections: the risk of side effects from gentamycin or furosemide is greater. Your doctor will only give you furosemide if it is essential.
- **Aminoglutethimide and Cisplatin to treat cancer:** Aminoglutethimide may cause a decrease of sodium in your blood. Furosemide may increase the side effects of cisplatin; your doctor may change your dose of furosemide.
- **Phenytoin** to control epilepsy (fits): furosemide may not work as well.
- **Carbamazepine** to control epilepsy: it may increase the side effects of furosemide if taken together.
- **Corticosteroids** used to treat allergic reactions and reduce inflammation (e.g. hydrocortisone): your salt balance may be altered causing your muscles to feel weak.
- **Reboxetine** for depression: your salt balance may be altered causing your muscles to feel weak.

- **Amphotericin** for fungal infections: your salt balance may be altered causing your muscles to feel weak.
- **Laxatives** used over a long period of time: your salt balance may be altered causing your muscles to feel weak.
- The effects of **curare-type muscle relaxants** (medicine that is used to relax muscles during surgery or other procedures) may be increased.
- **Theophylline** (to help against breathing difficulties): the effects may be increased.
- Certain **treatments for asthma e.g. salmeterol, salbutamol, terbutaline** (B<sub>2</sub>-sympathomimetics) when taken in large amounts: your salt balance may be altered causing your muscles to feel weak.
- **Probenecid** for gout: furosemide will not work as well or the effect of probenecid may be increased.
- **Methotrexate** for rheumatism or psoriasis: furosemide will not work as well or the effect of methotrexate may be increased.
- **Corticotrophin** a drug used to treat rheumatoid arthritis.
- **Ciclosporin** a drug used following organ transplant to suppress the immune system: can cause an increased risk of gouty arthritis (painful inflammation of the joints)
- **Radiocontrast agents** used in x-ray examinations: patients may experience deterioration in renal function.
- **Metolazone** (another diuretic): when taken together with furosemide can increase the amount of urine you pass which, in turn, could lead to dehydration.
- **Other diuretics e.g. amiloride**; when taken together with Furosemide your salt balance may be altered causing your muscles to feel weak.
- **Risperidone**: when taken with furosemide, you may have an increased risk of stroke or death in elderly people with dementia.
- **Aliskiren** for high blood pressure.

#### **Pregnancy, breast-feeding and fertility**

Do not take furosemide if you are pregnant. 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. If you become pregnant while taking furosemide, speak to your doctor as they will need to check the growth of your baby. Do not take furosemide tablets if you are breast-feeding.

#### **Driving and using machines**

**Do not** drive or operate machinery if you feel drowsy, dizzy or have blurred vision after taking furosemide.

#### **Furosemide Tablets contain lactose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **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.

#### **Adults**

- The recommended starting dose is 40 mg of furosemide once a day or on alternate days.
- Your doctor may adjust your dose gradually until you respond. You should NOT adjust the dose unless instructed to do so by your doctor.
- In very serious cases your doctor may ask you to take up to a maximum 1,500 mg per day.

#### **Elderly**

Your doctor may start you on a lower dose and gradually increase this dose.

### **Use in children**

- Your doctor will tell you the exact dose for your child based on your child's weight.
- The recommended dose is between 1–3 mg per kg of your child's weight.
- The maximum dose for children is 40 mg daily.

### **Method of administration**

Furosemide tablets are for oral use.  
Swallow the tablets with a drink of water.

### **If you take more Furosemide Tablets than you should**

If you take more medicine than your doctor has told you to, contact a doctor or your nearest hospital casualty department immediately and take your furosemide tablets with you. Taking too much furosemide tablets may make you feel confused, unable to focus, show a lack of emotion or interest in anything. You may also have dizziness, light headedness, fainting (due to low blood pressure), uneven heartbeat, muscle weakness or cramps and blood clots (signs include pain and swelling at the part of the body that is affected). You may also have problems with your kidneys or blood.

### **If you forget to take Furosemide Tablets**

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 double the amount to make up for a forgotten dose.

### **If you stop taking Furosemide Tablets**

Speak to your doctor before you stop taking furosemide tablets.

### **Blood Tests**

Your doctor may carry out blood tests to check that the levels of some salts in the blood are at the correct levels.

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 your medicine tell your doctor immediately or go to hospital straight away:**

- Severe allergic reaction which may include inflammation of the kidney (nephritis), a red and lumpy skin rash, severe blistering of the skin, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**
- Purple spotting or unexpected bruising of the skin
- Increased sensitivity to touch, skin prickling, skin is sensitive to sunlight
- Spasms, muscle twitching and cramps
- Inflammation of the pancreas which may cause severe pains in your abdomen or back, nausea, vomiting and fever
- You notice yellowing of your skin or eyes and your urine becomes darker in colour. These could be signs of a liver problem. In patients who already have liver problems, a more serious liver problem known as liver encephalopathy may occur. Symptoms include forgetfulness, fits, mood changes and coma.
- Swollen kidneys. 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. If symptoms become worse you may start to feel confused or go into a coma.
- Kidney stones in premature babies
- Inflammation of blood vessels, often with skin rash (vasculitis)

- You find it hard to urinate. This could be a symptom of acute urinary retention.
- Blood in your urine or pain in your abdomen or groin. This could be a disorder in which there is excess calcium deposited in the kidneys (nephrocalcinosis).
- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can lead to blood clots or 'gout'.
- Acute generalised exanthemateous pustulosis "(AGEP)" (acute febrile drug eruption) (frequency not known)
- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension) (frequency not known)
- Deafness (sometimes irreversible) (frequency uncommon)
- Furosemide can occasionally cause changes in your blood; your doctor will perform regular blood tests to ensure no changes have occurred. The symptoms of these changes include anaemia, leading to tiredness or lethargy, unusual bleeding or bruising, blood slow to clot, ulcers in your throat, mouth or on your skin. Changes in the blood can make you more likely to catch infections.
- **Other effects which may occur:**
- If you have diabetes, this may not be as well controlled
- Low blood pressure causing light-headedness, headache, dizziness, drowsiness, weakness, dry mouth or problems with your eyesight
- If this medicine is used in premature babies during the first weeks of life, it may cause persistence of a blood channel that normally closes at or around birth (PDA - patent ductus arteriosus). This may cause heart failure, failure to grow, shortness of breath, rapid breathing and rapid pulse.
- Skin reactions such as itching, marks on the skin, flaky or scaly skin
- Gout causing pain normally in the joints of your legs
- Hearing problems or ringing in your ears (tinnitus)
- Blood clots in the elderly
- If you have problems urinating furosemide may make this worse
- Sickness, vomiting, diarrhoea, or generally feeling unwell.
- Changes in natural body blood chemicals (sodium, chloride, potassium, calcium, magnesium, creatinine, urea, uric acid, water, cholesterol, triglycerides, liver enzymes such as transaminases and reduced glucose tolerance)
- Blood may become more alkaline (metabolic alkalosis)
- Inform your doctor if you have bone weakness (osteoporosis).

### **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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). 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.

Keep the container tightly closed. Store in the original container in order to protect from light.

Do not use this medicine after the expiry date which is stated on the label 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**

The active substance is furosemide. Each tablet contains 20 mg or 40 mg of furosemide.

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

### **What Furosemide looks like and contents of the pack**

- 20 mg tablet: White or almost white, circular, flat bevelled edge tablet with a breakline on one side.
- 40 mg tablet: White or almost white, circular, flat bevelled edge tablet with a breakline on one side.

### **Packaging:**

PP Containers with LDPE caps, in the following pack sizes:

Furosemide 20 mg tablets: 30, 100, 250, 500, 1000 and 5000 tablets

Furosemide 40 mg tablets: 30, 40, 100, 250, 500, 1000 and 5000 tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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