

## 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 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, pharmacist or nurse.
- 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 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 belongs to a group of medicines called diuretics, which increase the amount of urine passed by the kidneys, helping to remove excess fluids from the body. Diuretics are also known as 'water tablets'. Furosemide tablets are used in the treatment of oedema (fluid retention) caused by disorders of the heart, kidneys or liver alone or in combination with other anti-hypertensive agents. The tablets may also be used to treat pulmonary oedema (build up of fluid in the lungs) and mild to moderate hypertension (high blood pressure).

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

##### **Do not take Furosemide Tablets if:**

- you are allergic(hypersensitive) to Furosemide or any of the other ingredients in the tablets (these are listed in section 6) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you are allergic to amiloride, sulfonamides or sulphonamide derivatives, such as sulfadiazine or co-trimoxazole.
- you have been told that you have a low blood volume of fluid in your body or are dehydrated (with or without accompanying low blood pressure)
- you have been told by a doctor that you have kidney failure. In some types of kidney failure, it is still okay to have this medicine. Your doctor will be able to decide.
- you have severe problems with your liver (cirrhosis)

- you have electrolyte deficiency (e.g. Lower potassium or sodium levels in your blood as shown in blood test)
- you are not passing any water (urine).
- you have an illness called ‘Addison’s Disease’. This can make you feel tired and weak
- you are taking other medicines which change the amount of potassium in your blood (see ‘Other medicines and Furosemide Tablets’)
- your brain is not functioning properly (comatose and pre-comatose condition) linked to liver problems.
- you are children and adolescents under 18 years of age. Furosemide Tablets are not suitable for children.
- you are breastfeeding (see ‘Pregnancy, breast-feeding and fertility’ section below)
- you have porphyria (disease that affects how your body produces certain substances that help carry oxygen in your blood).

### **Warnings and Precautions**

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

- you have low blood pressure, your fluid electrolyte balance should be regularly monitored and the dose should be adjusted accordingly or feel dizzy when you stand up.
- you have diabetes. The amount of sugar in your blood may be monitored regularly
- you have difficulty in passing water (urine)
- you have gout
- you have liver or kidney problems
- you have low level of protein in your blood (hypoproteinaemia)
- you suffer from acute porphyria symptoms of which may include severe stomach, back or thigh pain. Nausea, vomiting or constipation may also present along with weakness in arms and legs.
- you are an elderly patient with dementia and are also taking risperidone
- you have prostate problems
- you feel dizzy or dehydrated. This can happen if you have lost a lot of water through being sick, having diarrhoea or passing water very often. It can also happen if you are having trouble drinking or eating
- you are going to have a glucose test
- you are taking any other water tablets
- you are going to give this medicine to a baby that was born too early.
- If you are elderly, if you are on other medications which can cause the drop the blood pressure and if you have other medical conditions that are risks for the drop of blood pressure.

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

### **Other medicines and Furosemide Tablets**

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

This is because Furosemide Tablets can affect the way some other medicines work. Also some medicines can affect the way Furosemide Tablets work.

**The following medicines can affect the way Furosemide Tablets work and increase the chance of you getting side effects. Your doctor may need to change your dose and/or to take other precautions if you are taking one of the following medicines:**

- Medicines such as ramipril, enalapril, perindopril (called ‘ACE inhibitors’) or losartan, candesartan, irbesartan (called ‘angiotensin II receptor antagonists’).
- Your doctor may need to change the dose of your tablets or ask you to stop taking them.
- Medicines for high blood pressure or heart problems. Your doctor may need to change the dose of your medicine.
- Medicines used to treat high blood pressure or prostate problems known as alpha-blockers, such as prazosin
- Other medicines used to treat high blood pressure and other medicines used to remove water from the body known as diuretics, such as amiloride, spironolactone, acetazolamide and metolazone
- Medicines which change the amount of potassium in your blood. These include potassium supplements such as potassium chloride or certain water tablets (diuretics).
- Medicines used to treat unusual heart beats, such as amiodarone, disopyramide, flecainide, lidocaine, tocainide, sotalol and mexiletine
- Medicines to help you sleep and relax such as chloral hydrate
- Medicines used as a general anaesthetic for relaxing your muscles during surgery. If you are going to have an anaesthetic please ensure that the doctor or nurse knows you are taking furosemide
- Medicines for diabetes. These may not work as well when you are taking Furosemide Tablets.
- Theophylline - used for wheezing or difficulty in breathing.
- Phenytoin - used for epilepsy. This can lower the effect of Furosemide Tablets.
- Medicines used for mental problems called ‘psychoses’, such as Risperidone, amisulpride, sertindole, pimozide and chlorpromazine. Avoid using pimozide at the same time as furosemide.
- Aliskiren – used to treat high blood pressure

**The following medicines can increase the chance of side effects when taken with Furosemide Tablets:**

- Lithium - used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood.
- Platinum compounds/Cisplatin - used for some cancers.
- Digitalis preparation and digoxin - used for heart problems. Your doctor may need to change the dose of your medicine.
- Non-steroidal anti-inflammatory drugs (NSAIDS) - used for pain and inflammation such as aspirin, ibuprofen, ketoprofen or indometacin.
- Carbamazepine - used for epilepsy.

- Aminoglutethimide - used for breast cancer.
- Ciclosporin, tacrolimus, aldesleukin - used to stop the rejection of organs after a transplant.
- Moxisylyte used to treat Raynaud's syndrome
- Medicines used to treat angina that you spray or dissolve under your tongue such as glyceryl trinitrate or isosorbide dinitrate
- Methotrexate - used for cancers of the skin, joint or bowel diseases.
- Carbenoxolone and sucralfate - used for ulcers of the food pipe (gullet).
- Reboxetine, amitriptyline and phenelzine - used for depression.
- Amphotericin - used for fungal infections if used for a long time
- Corticosteroids - used for inflammation such as prednisolone
- Atomoxetine used to treat Attention Deficit Hyperactivity Disorder (ADHD)
- Medicines to relax muscles such as baclofen and tizanidine
- Antihistamines, used to treat allergies such as cetirizine.
- Alprostadil, used to treat male impotence
- Oestrogen and drospirenone, used as contraceptives or in hormone replacement therapy (HRT)
- Liquorice - often used in cough medicines if taken in large amounts
- Probenecid (used with another HIV medicine)
- Medicines for infection such as gentamicin, amikacin, neomycin, netilmicin, tobramycin, vancomycin or high doses of cephalosporins
- Medicines used as injections before X-ray examinations (radio contrast agent)
- Medicines used for constipation (laxatives) if used for a long time such as bisacodyl or senna
- Medicines for asthma when given in high doses such as salbutamol, terbutaline sulfate, salmeterol, formoterol or bambuterol
- Medicines used to treat blocked noses, such as ephedrine and xylometazoline
- Potassium salts used to treat low potassium in the blood
- Medicines used to treat Parkinson's disease such as levodopa
- Other water tablets (diuretics) such as bendroflumethiazide. Your doctor may need to change the dose of your medicine
- Levothyroxine used to treat hypothyroidism, where your thyroid gland does not make enough of the hormone it needs

### **Furosemide tablets with food, drink and alcohol**

You should avoid drinking alcohol while taking Furosemide Tablets as this may lower your blood pressure further. It is recommended that Furosemide Tablets should be taken on an empty stomach.

### **Pregnancy and breast feeding and fertility**

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.

#### Pregnancy

Furosemide should only be used during pregnancy if your doctor deems it necessary. If furosemide is needed to treat heart or kidney problems during pregnancy, close monitoring of electrolytes, blood levels, and foetal growth of your unborn child is important.

#### Breast-feeding

Do not use furosemide during breast-feeding.

#### Fertility

No data is available on the effect of furosemide on fertility.

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

This medicine may make you feel dizzy or unwell. Do not drive or operate machinery if this happens.

#### **Furosemide Tablets contains 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.

#### ***Information on sodium content:***

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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The number of tablets you need will depend on your condition. The tablets should be swallowed whole with a glass of water
- You should take the tablets at approximately the same time each day before a meal or as directed by your doctor

#### ***Adults and elderly:***

The usual dose is one or two tablets first thing in the morning. Your doctor will tell you how many tablets to take.

#### ***Children and adolescents (under 18 years of age):***

Not recommended as safety in this age group has not yet been established.

**If you are taking sucralfate** (a medicine for stomach ulcers). Do not take sucralfate at the same time as Furosemide Tablets. Take your dose at least 2 hours before or after Furosemide Tablets. This is because it can affect the way your medicine works.

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

If you or a child accidentally take too many tablets, tell your doctor immediately or contact your nearest Hospital Casualty/Accident and Emergency department even if there are no signs of discomfort. Take the medicine in its original packaging with you in order to enable the doctor identify your medication easily. 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 body that is affected). You may also have problems with your kidneys or blood.

**If you forget to take Furosemide Tablets**

Take the missed dose as soon as you remember, unless it is evening, in which case if you do take the missed dose you may need to get up in the night to pass water. Take your next dose at the usual time.

**DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR A FORGOTTEN DOSE.**

**If you stop taking Furosemide Tablets**

Keep taking Furosemide tablets until your doctor tells you to stop taking it.

**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, pharmacist or nurse.

**4. Possible Side Effects**

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

**STOP TAKING** this medicine and tell your doctor immediately if you suffer from any of the following

- Severe allergic reactions such as itching, skin rash with severe itching and nettle rash, fever, allergic to light, severe allergic reaction with (high) fever, red patches on the skin, joint pain and/or inflammation of the eyes, severe, acute (allergic) reaction accompanied by fever and blisters on the skin/peeling skin and tiny spots from bleeding in the skin.
- sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen, shifting towards the back.

The other side effects are:

**Very common (may affect more than 1 in 10 people):**

- Electrolyte imbalance (including symptomatic),
- dehydration and low blood volume (hypovolemia), especially in elderly patients,
- increased levels of creatinine and blood urea (seen in the blood test),
- increased levels of triglycerides in the blood
- lower blood pressure, especially when standing up quickly (orthostatic hypotension)

**Common (may affect up to 1 in 10 people):**

- Low chloride levels,
- High blood cholesterol levels,
- High levels of uric acid in the blood, which may lead to gout
- Abnormal high concentration of blood
- Excessive loss of fluids (e.g. passing urine more often than normal) and minerals (sodium, potassium, magnesium, calcium). Symptoms that can occur are thirst, headache, confusion, muscle cramps, increased irritability of the muscles, muscular weakness, heart rhythm disturbances and gastrointestinal problems such as sensation of unease and discomfort in stomach with an urge to vomit, or diarrhoea.

**If you have a shortage of sodium (sodium deficiency):**

- cramp in the calf muscles
- loss of appetite
- listlessness
- feeling of weakness
- dizziness
- drowsiness
- confusion

**If you have a shortage of potassium (potassium deficiency):**

- muscular weakness and the inability to contract one or more muscles (paralysis)
- increased excretion of urine
- heart problems
- in the case of severe potassium deficiency: interference with the function of the intestine or confusion, which can result in coma

**If you have a shortage of magnesium and calcium (magnesium and calcium deficiency):**

- increased irritability of the muscles
- heart rhythm disturbances
- Lowering of blood pressure, resulting in impaired concentration and reactions, light-headedness, a feeling of pressure in the head, headache, dizziness, drowsiness, a feeling of weakness, visual disturbances, dry mouth and an inability to stand upright

**Uncommon (affects 1 to 10 users in 1,000)**

- abnormal blood count accompanied by bruising and a tendency to bleed
- sensitivity to light (photosensitivity reactions)
- involuntary leakage of urine
- in the elderly, this can lead to a low blood volume, fluid depletion and thickening of the blood. This can cause clots to form in the blood
- deafness (sometimes irreversible), hearing disorders
- Decrease in glucose tolerance.
- Nausea
- Low levels of protein in blood (hypoproteinemia)
- Changes in vision including blurred or yellow vision

**Rare (affects 1 to 10 users in 10,000)**

- · 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
- increase in certain substances (eosinophilic cells) in the blood
- a crawling sensation on the skin, itching or tingling without any reason
- a life-threatening form of unconsciousness
- hearing disorders & ringing in the ears. These disorders are usually temporary in nature
- inflammation of a blood vessel
- acute kidney failure
- inflammation of the kidneys associated with blood in the urine, fever and pain in the sides. If you have a urinary tract obstruction, increased urine production may occur or worsen
- if you have a bladder disorder, enlarged prostate or narrowing of the ureters, urine production can stop suddenly
- severe anaphylactic shock (severe drop in blood pressure, extreme paleness, restlessness, weak fast pulse, clammy skin, impaired consciousness) as a result of a sudden severe dilatation of the blood vessels due to allergy to certain substances
- fever
- minor mental disturbances
- Vomiting
- Diarrhoeas

**Very rare (affects less than 1 user in 10,000)**

- Decrease in white blood cells
- anaemia (a condition characterised by shortage of red blood cells)
- very severe blood abnormality (white blood cell deficiency) accompanied by a sudden high fever, severe throat pain and ulcers in the mouth
- certain liver function disorders, Cholestasis
- increase in certain liver enzymes, increased transaminase levels
- condition that affects brain function due to liver disease

During treatment with furosemide, the blood levels of some fats (cholesterol and triglyceride) may rise, but usually return to normal within 6 months

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

- acute generalised exanthematous pustulosis (AGEP)” (acute febrile drug eruption)
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- high pH levels,
- Yeydo-Bartter syndrome in the context of misuse and /or long-term use of furosemide.
- Increase in risk of blood clots
- Increased levels of sodium in the urine,
- urinary retention (in patients with partial obstruction of urine outflow)
- Kidney damage (interstitial nephritis)

If this medicine is used in babies born too soon (prematurely), this medicine can cause:

- persistence of a blood channel that normally closes at or around birth. This may cause heart failure, failure to grow, shortness of breath and rapid pulse
- kidney stones and/or calcium deposits in the body

**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 HPRC Pharmacovigilance [www.hpra.ie](http://www.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.
- Containers and blister carton: Do not store above 25°C. Store in the original packaging and keep the packaging tightly closed.
- Do not use this medicine after the expiry date which is 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 protect the environment.

**6. Contents of the pack and other information**

**What Furosemide Tablets contains**

- The active substance is furosemide. This is the new name for frusemide. The ingredient itself has not changed.

- Furosemide Tablets come in two strengths 20mg and 40mg. Each tablet contains either 20 mg or 40 mg of the active ingredient.
- The other ingredients are: lactose monohydrate, maize starch, pregelatinized maize starch, sodium starch glycollate and magnesium stearate.

#### **What Furosemide Tablets look like and contents of the pack**

- Furosemide 20mg tablets are round, white to off circular white tablets marked 'F 20' on one side and 'BL' on the other.
- Furosemide 40mg tablets are round, white to off circular white tablets marked 'F 40' separated by a break line on one side and 'BL' on the other.
- The tablets are supplied in blister packs containing 28, 30, 50, 56, 84, 98 & 100 tablets and containers containing 100, 250, 500 & 1000 tablets. Not all pack sizes may be marketed.

#### **Marketing authorisation Holder**

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This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands : Furosemide 20mg Tabletten  
Furosemide 40mg Tabletten  
United Kingdom : Furosemide 20mg Tablets  
Furosemide 40mg Tablets

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