PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

LASIX 20 mg tablets

LASIX 40 mg tablets

LASIX 80 mg tablets

Furosemide

LASIX 20 mg contains sugar (26,50 mg lactose monohydrate).

LASIX 40 mg contains sugar (53,00 mg lactose monohydrate).

LASIX 80 mg contains sugar (106,00 mg lactose monohydrate).

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- LASIX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LASIX is and what it is used for.
2. What you need to know before you take LASIX.
3. How to take LASIX.

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

1. What LASIX is and what it is used for

LASIX contains the active ingredient furosemide.

Furosemide belongs to a group of medicines called diuretics. Diuretics are sometimes called ‘water tablets’. Diuretics are used to remove excess fluid from your body by making you pass more urine.

2. What you need to know before you take LASIX

Do not take LASIX:

- If you are hypersensitive (allergic) to furosemide or any of the other ingredients of LASIX (listed in section 6).
- If you are hypersensitive (allergic) to sulfonamides, such as sulfadiazine or co-trimoxazole.
- If your doctor has told you that you have a low blood volume, low blood pressure or are dehydrated.
- If you have been told by a doctor that you have kidney failure. In some types of kidney failure, it is still acceptable to take LASIX. Your doctor will be able to decide.
- If you have severe liver problems.
- If you are not passing any water (urine).
- If you have low potassium or sodium levels in your blood (determined by a blood test).
- If you are breastfeeding (see “Pregnancy and breastfeeding”).

Do not use LASIX if any of the above applies to you. If you are not sure, talk to your doctor or

pharmacist before taking LASIX.

Warnings and precautions

Take special care with LASIX if:

- You have difficulty in passing water (urine).
- You are 65 years of age or older.
- You have liver or kidney problems.
- You have diabetes (high blood sugar).
- You have low blood pressure or feel dizzy when you stand up.
- You are male and you have prostate problems.
- You have gout.
- You feel dizzy or feel 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, or are sweating excessively, such as during strenuous exercise.
- You are going to have a glucose test.
- You have a condition called lupus erythematosus.

It is recommended to undergo regular monitoring of blood levels for sodium, potassium, kidney function (creatinine levels) while taking LASIX.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking LASIX.

Other medicines and LASIX

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

The following medicines can affect the way LASIX works and increase the chance of you getting side effects:

- Medicines such as ramipril, enalapril, perindopril (called angiotensin-converting enzyme [ACE] inhibitors) or losartan, candesartan, irbesartan (called angiotensin II receptor antagonists), used to treat high blood pressure. Your doctor may need to change the dose of your medicine or ask you to stop taking it.
- Medicines for high blood pressure or heart problems. Your doctor may need to change the dose of these medicines.
- Medicines used as a general anaesthetic for relaxing your muscles during surgery.
- Medicines for diabetes. These may not work as well when you are taking LASIX.
- Theophylline (used for wheezing, cough or difficulty in breathing).
- Lithium (used as a mood stabiliser or to treat mental illness). To help stop the side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood.
- Cisplatin (used to treat some cancers).
- Digoxin (used to treat heart problems). Your doctor may need to change the dose of digoxin.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (used to treat pain, fever and inflammation), such as aspirin, ibuprofen, ketoprofen or indomethacin.
- Phenytoin (used to treat epilepsy and seizures [fits]).
- Ciclosporin (used to prevent the rejection of organs after a transplant).
- Corticosteroids, such as prednisone (used to treat inflammation).

- Antibiotics (used to treat bacterial infection), such as gentamicin, amikacin, neomycin, netilmicin, tobramycin, vancomycin or high doses of cephalosporins.
- Medicines used as injections for x-ray examinations.
- Medicines used for constipation (laxatives) if used for a long time, such as bisacodyl or senna.
- Other water tablets (diuretics) such as hydrochlorothiazide. Your doctor may need to change the dose of your LASIX.
- Chloral hydrate (used as a sedative and for insomnia).
- Sucralfate (used to treat duodenal ulcers).
- Risperidone (used to treat schizophrenia and bipolar disease).
- Medicines that have a poisonous effect on the kidneys.
- Liquorice, often used in cough medicines if taken in large amounts.
- Probenecid (used to treat gout), as it may reduce the effect of LASIX.
- Levothyroxine (used to treat an underactive thyroid gland).
- Aliskiren (used to treat high blood pressure).
- Methotrexate (used to treat autoimmune diseases, rheumatoid arthritis and some cancers).

Pregnancy and breastfeeding

Do not take LASIX if you are pregnant.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking LASIX.

Do not breastfeed if you are taking LASIX. This is because small amounts may pass into the mother’s milk.

Driving and using machinery

LASIX may cause side effects, such as dizziness and low blood pressure, which may affect your ability to drive a vehicle or use machines (see “Possible side effects”). Do not drive a vehicle or use machinery until you know how LASIX affects you.

LASIX contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LASIX tablets.

3. How to take LASIX

Do not share medicines prescribed for you with any other person.

Always take LASIX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

How to take LASIX 20 mg, 40 mg and 80 mg tablets

The recommended initial oral dose is 20 mg to 80 mg daily. This may be adjusted as necessary according to response.

It is recommended that LASIX tablets be taken on an empty stomach. Swallow the tablets without chewing, with sufficient amounts of liquid.

LASIX should preferably be taken in the morning and at the about same time each day.

Your doctor will tell you how long your treatment with LASIX will last. If you have the impression that the effect of LASIX is too strong or too weak, tell your doctor or pharmacist.

If you take more LASIX than you should

In the event of overdosage, tell your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the remaining LASIX with you so the doctor will know what you have taken.

If you forget to take LASIX

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

4. Possible side effects

LASIX can have side effects.

Not all side effects reported for LASIX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LASIX, please consult your health care provider for advice.

If any of the following happens, stop taking LASIX and tell your doctor immediately or go the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to LASIX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Severe pain in your stomach area radiating to your back. This could be a sign of pancreatitis.
- Severe skin and mucous membrane reactions, for example with blisters or skin detachment (Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis [AGEP] [acute febrile drug eruption], drug eruption with eosinophilia and systemic symptoms); lichenoid reactions that manifest as small, itchy, reddish-purple, uneven changes to the skin, genitals or in the mouth.
- Unexplained bleeding, bruising more easily, frequent infections (including fever, severe chills, sore throat), or feeling weaker or more tired than usual. LASIX can affect the number of blood cells, causing serious blood problems.
- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upset 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.
- Yellowing of your skin or eyes, or 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.
- Kidney failure (drowsiness, shortness of breath, fatigue, confusion, nausea, fits, passing less urine than is normal for you).
- Embolism (difficulty breathing, chest pains, light-headedness, dizziness, numbness, confusion, difficulty walking or talking, fast heartbeat, sweating, feeling anxious, coughing up blood or pink, foamy mucus).
- Kidney problems and difficulty passing urine.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Too low levels of sodium in your blood (shortness of breath, headache, dizziness, confusion, coma).
- Too low levels of potassium in your blood (abnormal or slow heart rate, low blood pressure, cramps, weakness).
- LASIX can decrease the levels of chloride in your blood.
- LASIX can increase the levels of creatinine in your blood.
- Feeling dizzy or light-headed when standing up quickly from a lying or sitting position. This could be due to low blood pressure.
- An increase in the volume of urine you produce.
- Increased uric acid levels, which may cause gout attacks (warmth, pain swelling in a joint, usually the big toe).

Less frequent side effects:

- If you have diabetes, you may be less able to control the levels of glucose in your blood.
- Dry mouth.
- Tingling or numbness of your hands and feet (pins and needles).
- Problems hearing or ringing in your ears (tinnitus). This especially affects people who already have problems with their kidneys.
- Deafness, which could be permanent.
- Feeling sick (nausea), being sick (vomiting) and diarrhoea.
- Erythema multiforme (red, often itchy spots, which starts on the limbs and sometimes spreads to the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea).
- Purple spots on your skin caused by bleeding from small blood vessels.
- Increased sensitivity of your skin to the sun.
- Fever.

- Vasculitis (inflammation of your blood vessels, causing fever, general aches and pains, night sweats, headache, fatigue and weight loss).

Side effects with an unknown frequency:

- Blood clotting problems (pain, swelling and tenderness in one of your legs, warm skin in the area of the clot, red skin).
- Worsening of systemic lupus erythematosus.
- Decreased levels of calcium or magnesium in your blood (muscle weakness, muscle tightness, tremors, or twitches, irritability or insomnia, numbness and tingling, severe drowsiness, fatigue, and confusion, fast or irregular heart rate, seizures).
- Unusual muscle movements, such as jerking, twitching or muscle spasm, muscle cramps.
- Muscle injury resulting in muscle pain in your shoulders, thighs, or lower back.
- Vertigo (spinning sensation or loss of balance), visual impairment, feeling pressure in your head.
- People with bladder and prostate problems may notice urine retention (your bladder does not empty all the way).
- Headache, dizziness and fainting.

Blood tests:

LASIX can change the levels of liver enzymes or body fats known as cholesterol and triglycerides.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.safety@sanofi.com (email), https://ae.reporting.sanofi/ (web portal) or +27 11 256 3700 (tel)

or

- SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website.

By reporting side effects, you can help provide more information on the safety or LASIX.

5. How to store LASIX

- LASIX 20 mg, 40 mg and 80 mg tablets in amber glass bottles: Store at or below 25 °C and protect from light.
- LASIX 40 mg tablets in blister strips: Store at or below 30 °C and protect from light.
- Do not use LASIX if you notice a yellowish discolouration of the tablets.
- Store all medicines out of reach of children.
- Do not store medicines in the bathroom.
- Do not use your medication after the expiry date shown on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LASIX contains

The active substance is furosemide.

LASIX 20 mg: Each tablet contains 20 mg furosemide.

LASIX 40 mg: Each tablet contains 40 mg furosemide.

LASIX 80 mg: Each tablet contains 80 mg furosemide.

The other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate, maize starch and talc.

What LASIX looks like and contents of the pack

LASIX 20 mg: A white round, scored tablet with the company logo on the one side, and coded DLF on the other side.

LASIX 40 mg: Almost white, round, biplanar, scored tablet with a unilateral score line and engraved DLI on each side of the score line. The other face is engraved with the logotype ‘Hoechst’.

LASIX 80 mg: White, round, bevelled-edge tablet, 8-faceted, with a score line and “LASIX 80” imprinted on one side and the company logo on the other side.

LASIX 20 mg: Amber glass bottle with a white screw cap, containing 30 tablets.

LASIX 40 mg: Amber glass bottle with a white screw cap, containing 30 tablets or 250 tablets.

Bottle-green PVC/aluminium blisters strips containing 15 tablets each and packed in an outer carton.

Pack size of 30 tablets.

LASIX 80 mg: Amber glass bottle with a white screw cap, containing 30 tablets or 100 tablets.

Holder of Certificate of Registration

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Namibia:

Scheduling status: NS2

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Lasix 20 mg: 90/18.1/00315

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Botswana:

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Reg. no.:

Lasix 20 mg: B9315570

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