PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

LASIX ORAL SOLUTION (10 mg/mL)

Furosemide

Contains sorbitol (a sugar alcohol): 245 mg per mL.

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

- 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 ORAL SOLUTION is and what it is used for.
2. What you need to know before you take LASIX ORAL SOLUTION.
3. How to take LASIX ORAL SOLUTION.
4. Possible side effects.
5. How to store LASIX ORAL SOLUTION.
6. Contents of the pack and other information.

1. What LASIX ORAL SOLUTION is and what it is used for

LASIX ORAL SOLUTION contains the active ingredient furosemide.

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

LASIX ORAL SOLUTION is for use in children, or adults who have difficulty swallowing tablets.

2. What you need to know before you take LASIX ORAL SOLUTION

Do not take LASIX ORAL SOLUTION:

- If you are hypersensitive (allergic) to furosemide or any of the other ingredients of LASIX ORAL SOLUTION (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 ORAL SOLUTION. 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 ORAL SOLUTION if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking LASIX ORAL SOLUTION.

Warning and precautions

Take special care with LASIX ORAL SOLUTION 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 ORAL SOLUTION.

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

Other medicines and LASIX ORAL SOLUTION

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 ORAL SOLUTION 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 ORAL SOLUTION.
- 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 ORAL SOLUTION.
- 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 ORAL SOLUTION.
- 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 ORAL SOLUTION 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 ORAL SOLUTION.

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

Driving and using machines

LASIX ORAL SOLUTION 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 ORAL SOLUTION affects you.

LASIX ORAL SOLUTION contains alcohol (ethanol)

LASIX ORAL SOLUTION contains 96 mg of alcohol (ethanol) in each 1 mL which is equivalent to 9,6 % *w/v*. The amount in 1 mL of this medicine is equivalent to less than 2,4 mL beer or 0,96 mL wine. The small amount of alcohol in LASIX ORAL SOLUTION will not have any noticeable effects.

LASIX ORAL SOLUTION contains sorbitol

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take LASIX ORAL SOLUTION. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

LASIX ORAL SOLUTION contains preservatives and azo colourants

LASIX ORAL SOLUTION contains methylparaben and propylparaben as preservatives, as well as Sunset Yellow FCF as a colourant, which may cause allergic reactions (possibly delayed).

LASIX ORAL SOLUTION contains sodium

LASIX ORAL SOLUTION contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially ‘sodium free’.

3. How to take LASIX ORAL SOLUTION

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

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

How to take LASIX ORAL SOLUTION

The usual oral dose is 20 mg to 80 mg taken once daily. This may be increased as necessary according to response.

After oedema (swelling) has been controlled, the usual dose is 20 mg to 40 mg daily.

If the daily dose exceeds 120 mg, the doses should be distributed over two to three individual doses.

For the treatment of hypertension (high blood pressure), the usual daily dose is 40 mg to 80 mg taken once daily. A lower dose may be prescribed depending on other medicines also taken to lower blood pressure.

In infants and children under 15 years, the usual dose is 2 mg/kg body mass, given in divided doses. The maximum daily dose is 40 mg given in divided doses. The dose may be prescribed up to a maximum of 6 mg/kg per day.

It is recommended that LASIX ORAL SOLUTION be taken on an empty stomach.

LASIX ORAL SOLUTION 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 ORAL SOLUTION will last. If you have the impression that the effect of LASIX ORAL SOLUTION is too strong or too weak, tell your doctor or pharmacist.

If you take more LASIX ORAL SOLUTION than you should

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

If you forget to take LASIX ORAL SOLUTION

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 ORAL SOLUTION can have side effects.

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

If any of the following happens, stop taking LASIX ORAL SOLUTION 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 ORAL SOLUTION. 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 more than usual. LASIX ORAL SOLUTION 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 ORAL SOLUTION can decrease the levels of chloride in your blood.
- LASIX ORAL SOLUTION 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, similar to the rash of measles 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 ORAL SOLUTION 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 ORAL SOLUTION.

5. How to store LASIX ORAL SOLUTION

- Store between 2 °C and 8 °C in refrigerator.
- Do not freeze.
- Protect from light.
- Once opened, the contents of the bottle remain stable for a period of 60 days under refrigerated conditions.
- 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 or bottle.
- 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 ORAL SOLUTION contains

The active substance is furosemide.

Each 1 mL of LASIX ORAL SOLUTION contains 10 mg furosemide.

The other ingredients are alcohol, glycerol, methylparaben, natural orange flavour, propylparaben, Quinoline Yellow (colourant), sodium hydroxide, sorbitol solution and Sunset Yellow (colourant).

Alcohol: 9,6 % *v/v*.

Preservatives: methylparaben 0,25 % *v/v*, propylparaben 0,05 % *v/v*.

What LASIX ORAL SOLUTION looks like and contents of the pack

A clear, orange-yellow solution with an orange flavour in an amber glass bottle with a screw cap.

Pack size: 100 mL amber glass bottles.

Holder of Certificate of Registration

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