

## IMPORTANT: PLEASE READ

### PART III: CONSUMER INFORMATION

Pr LASIX® SPECIAL  
(furosemide tablets, Manufacturer standard)

This leaflet is part III of a three-part "Product Monograph" published for LASIX® SPECIAL in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about LASIX SPECIAL. Contact your doctor or pharmacist if you have any questions about the drug.

#### ABOUT THIS MEDICATION

**What the medication is used for:**  
LASIX SPECIAL IS A HIGH-DOSE MEDICATION INTENDED EXCLUSIVELY FOR PATIENTS WITH SEVERELY IMPAIRED KIDNEY FUNCTION. LASIX SPECIAL IS TO BE USED UNDER STRICT MEDICAL SUPERVISION IN A HOSPITAL SETTING.

LASIX SPECIAL may be used as an aid in the treatment of conditions such as kidney disease, low urine production, edema (water retention), acute/chronic kidney failure before starting on dialysis and once on dialysis for patients with continued water in their lungs (pulmonary edema).

**What it does:**

LASIX SPECIAL belongs to a group of medicines known as diuretic drugs which improve the elimination of water and salts (electrolytes) in the urine.

**When it should not be used:**

Do not use LASIX SPECIAL

- If you are allergic to it or to any of the components of its formulation (for list of components see the section on "What the non-medicinal ingredients are").
- If you are allergic to any sulfonamide-derived drugs. Ask your physician or pharmacist if you are not sure what sulfonamide-derived drugs are.
- If you have hypokalemia (low potassium blood levels).
- If you have hyponatremia (low sodium blood levels).
- If you have low blood pressure.
- If you have dehydration.

- If you have kidney disease/increased or decreased kidney functioning.
- In newborn babies with jaundice (yellowing of the skin or eyes) or Rh incompatibility.
- If you are pregnant or breastfeeding.

Before using LASIX SPECIAL, tell your health provider if you have any of the following conditions so he can carefully consider the risks and benefits of a treatment with LASIX SPECIAL:

- Any liver disease
- Urinary retention (difficulty to urinate)

**What the medicinal ingredient is:**

Furosemide

**What the nonmedicinal ingredients are:**

**500 mg tablets:** Colloidal silicon dioxide, D&C Yellow #10, FD&C Yellow #6, lactose monohydrate, magnesium stearate, powdered cellulose, sodium starch glycolate, corn starch, and talc.

**What dosage forms it comes in:**

Tablets of 500 mg

#### WARNINGS AND PRECAUTIONS

LASIX SPECIAL IS A VERY STRONG WATER PILL WHICH IF GIVEN IN EXCESSIVE AMOUNTS CAN LEAD TO A PROFOUND WATER AND ELECTROLYTE LOSS FROM THE BODY. THEREFORE, CAREFUL MEDICAL SUPERVISION IS REQUIRED. THE DOSE AND DOSE SCHEDULE HAVE TO BE ADJUSTED TO THE INDIVIDUAL PATIENT'S NEEDS. BEFORE you use LASIX SPECIAL, talk to your health provider if:

- You have decreased blood pressure.
- You have liver disease or disorder.
- You have kidney disease or disorder.
- It is suspected you might be diabetic (high blood sugar).
- You have decreased ability to pass urine.
- You had an organ transplant.
- You have gout.
- You have lupus or had a medical history of an episode of lupus.
- You have been told by the doctor that you suffer from a narrowing of the arteries that supply your heart or brain.
- You have recently suffered from excess vomiting or diarrhea.
- You intend to have a surgery and general

## IMPORTANT: PLEASE READ

anesthesia (even at the dentist's office), as there may be a sudden fall in blood pressure associated with general anesthesia.

- You are breast feeding, pregnant, or think you might be pregnant.
- You intend to change your eating habits.
- You are less than 16 years old.
- You are older than 61 years old.

For elderly patients, (over 61 years old), the dose selection should be cautious, usually starting at the low end of dosage range, reflecting the greater frequency of decreased liver, kidney or heart function.

Studies in elderly patients with dementia have shown that taking LASIX SPECIAL with risperidone is associated with a higher rate of death.

The administration of LASIX SPECIAL to diabetic patients may result in possible decrease of diabetic control. Dosage adjustments of the antidiabetic agent may be needed. There have been cases of ringing in the ears, reversible and non-reversible deafness especially in children. This is most true when the patient has severe kidney disease or is taking drugs that are known to sometimes damage the ears while they are taking LASIX SPECIAL. Your doctor will decide if LASIX SPECIAL is the right medication for you based on your particular condition.

LASIX SPECIAL should not be used in pregnant women or in women of childbearing potential unless in the opinion of the attending physician the benefits to the patient outweigh the possible risk to the foetus. Treatment during pregnancy requires monitoring of fetal growth by your doctor.

If you are suffering from hyperuricemia (high uric acid levels in your blood), taking LASIX SPECIAL can sometimes make a gout attack more likely.

Almost all patients can drive or operate machinery while taking LASIX SPECIAL, but you should not perform these tasks, which may require attention, until you know how you tolerate your medicine.

### INTERACTIONS WITH THIS MEDICATION

Before using LASIX SPECIAL, tell your health provider about medication you are currently taking.

This way appropriate adjustment and decision can be taken for your treatment with LASIX SPECIAL.

Below are drugs or drug classes that may interact with LASIX SPECIAL. These include:

- Drugs to reduce blood pressure (eg. ACE inhibitors, angiotensin II receptor antagonist).
- Diuretics (waterpills), including ethacrynic acid
- Pressor amines such as epinephrine (a medication used to treat life-threatening allergic reactions)
- Medication to treat diabetes, including insulin. The administration of LASIX SPECIAL to diabetic patients may result in possible decrease of diabetic control. Dosage adjustments of the antidiabetic agent may be needed.
- Theophylline, a medication used to treat asthma, chronic bronchitis, and other lung diseases.
- Cisplatin (anti-cancer drug)
- Probenecid (medicine used to treat gout).
- Antibiotics (e.g cephalosporines, aminoglycosides)
- Certain pain and anti-inflammatory drugs (e.g non-steroidal anti-inflammatory drugs [NSAIDs], acetyl-salicylic acid, indomethacin).
- Drugs used in the treatment of rheumatoid arthritis (methotrexate, cyclosporin).
- Drugs used to treat epilepsy (e.g. phenytoin, carbamazepine, phenobarbital).
- Risperdal, a drug used to treat dementia.
- Lithium (medicine used to treat bipolar depression).
- Sucralfate (antacid drug).
- Sedatives such as phenobarbital or chloral hydrate.
- Stimulant laxatives and drugs which may induce low potassium levels (hypokalemia) such as glucocorticoids, and medicine derived from licorice (eg. carbenoxolone) .
- Drugs known to be harmful to the ear (ototoxic) as for instance aminoglycosides antibiotics, ethacrynic acid (a "water pill") and cisplatin (a drug used to treat some types of cancer).
- Drugs known to be harmful to the kidney.
- Substances used during certain radiological investigations (radiocontrast agents).
- Digitalis (digoxin)
- Certain steroids-
- Levothyroxine, a drug used to adjust your thyroid hormone levels.

## IMPORTANT: PLEASE READ

### PROPER USE OF THIS MEDICATION

LASIX SPECIAL is to be used under strict medical supervision in a hospital setting.

During long-term therapy a high-potassium diet may be recommended. You should not be on a strict salt restricted diet. Potassium supplements may be required. Your doctor will monitor your blood tests for blood sugar, potassium and other electrolytes and to monitor liver and kidney function. This is especially important if you have other medical conditions such as diabetes, or take other medications.

#### Usual dose:

It is important that you take LASIX SPECIAL as prescribed by your doctor.

Your doctor will prescribe LASIX SPECIAL at an individualized dose, based on your condition.

Maximum daily dose: 1000 mg.

Take the tablets without chewing with a glass of water.

You should always respect the prescribed interval between the doses. Never change the dose of LASIX SPECIAL you are taking unless your doctor tells you to.

This drug is specifically prescribed for you. Do not give it to others, even if they have the same symptoms, and you must not use it for any condition than the one for which it was prescribed.

#### Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its beneficial effects, LASIX SPECIAL like all other drugs may sometimes cause undesirable effects. These may include: blurring of vision, constipation, diarrhea, dizziness, dry mouth, fatigue, tachycardia, arrhythmia (heart rhythm disturbance),

feeling of pressure in the head, increase in the amount and frequency of your urine, leg cramps, mental confusion, nausea, sweating, thirst, vomiting, hepatic encephalopathy (altered mental state due to liver disease). Talk to your doctor or pharmacist if you experience any of the above.

Stop taking LASIX SPECIAL and contact your doctor immediately if you experience an allergic reaction or any severe side effect.

### SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist immediately		Stop taking drug and seek immediate medical attention
	Only if severe	In all cases	
Hearing problems; deafness, sometimes non-reversible		✓	
Fever, sore throat, fatigue, lesions in the mouth or on the lips			✓
Skin rash and/or blistering			✓
Hives and/or itching			✓
Abdominal pain		✓	
Difficulty to urinate			✓
Low blood pressure (hypotension): dizziness when rising to a standing position, impaired concentration and lightheadedness		✓	
Yellow coloration of the skin (jaundice)			✓
Dehydration and/or abnormal blood tests: dryness of the mouth, thirst, weakness, dizziness, fainting or loss of consciousness, lethargy, drowsiness, restlessness, muscle pain or cramps, muscular fatigue, hypotension, racing or irregular heartbeats, nausea and vomiting, sweating, increases in blood sugar levels, increased urination, mental confusion, headache			✓

## IMPORTANT: PLEASE READ

### SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist immediately		Stop taking drug and seek immediate medical attention
	Only if severe	In all cases	
Muscle problems: unexplained muscle pain, tenderness, weakness, cramps		✓	
Pseudo –Bartter syndrome: abnormal blood tests, fatigue, muscle weakness, diarrhea, dehydration, increased thirst, increased urination, low blood pressure, irregular heartbeats			✓
Blurred vision		✓	
Allergic reactions: eyes sensitive to light, tingling of fingers or toes, fever			✓
Blood clots: pain, swelling tenderness in your leg or arm, warm, red skin and a heavy feeling in the affected area			✓
Failure of the kidneys: weakness, trouble breathing, swelling, fast or irregular heartbeat, confusion, decrease or inability to urinate, loss of appetite, coma and death			✓
In premature babies: discoloured urine and/or blood in the urine/diaper, fever and chills, vomiting, excessive crying or other signs the baby is in pain			✓
In premature babies: poor weight gain		✓	

Although not all of the above side effects are common, if you experience one of these while you are in the hospital or at home, talk to your doctor or pharmacist immediately.

*This is not a complete list of side effects. For any unexpected effects while taking LASIX SPECIAL, contact your doctor or pharmacist.*

### HOW TO STORE IT

Store your tablets at room temperature (15° – 25°C). Protect from light.

There is an expiration date on the label. Do not use the medicine after this date.

Return any leftover tablets to the pharmacist, unless the doctor tells you to keep them at home.

As with all medicines, keep LASIX SPECIAL out of reach of children.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at [www.sanofi.ca](http://www.sanofi.ca) or by contacting the sponsor, sanofi-aventis Canada Inc. at: 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last revised: February 20, 2018