

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrLASIX® SPECIAL

Furosemide tablets

Read this carefully before you start taking **LASIX SPECIAL** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LASIX SPECIAL**.

Serious Warnings and Precautions

- LASIX SPECIAL is a strong diuretic. Diuretics are also known as “water pills”. Taking too much LASIX SPECIAL can cause you to lose too much water and too many electrolytes. You must be supervised by a healthcare professional while taking this medicine. Your healthcare professional will adjust your dose and your dosing schedule to treat your particular condition.
- LASIX SPECIAL may worsen or activate lupus (an autoimmune disease) in patients who have lupus or have had an episode of lupus. See the Serious side effects and what to do about them table for more information about this serious side effect.

What is LASIX SPECIAL used for?

- LASIX SPECIAL is used to help treat low urine output and excess fluid buildup in the body (edema) due to:
 - sudden kidney failure (a common complication of major surgery or sepsis);
 - chronic kidney failure with excess fluid buildup in the body, especially in the lungs (pulmonary edema). LASIX SPECIAL can be used before there is a need for dialysis or during dialysis;
 - a kidney disorder called nephrotic syndrome, which causes your body to pass too much protein in your urine, combined with a severe loss in kidney function (e.g., due to chronic glomerular nephritis, lupus erythematosus, or Kimmelstiel-Wilson syndrome).
- LASIX SPECIAL is a high-dosage formulation of furosemide. It is intended only in patients with severe kidney problems. A healthcare professional will supervise you while you take this medicine in the hospital.

How does LASIX SPECIAL work?

LASIX SPECIAL belongs to a group of medicines called diuretics. It works by removing excess water from the body by making the kidneys produce more urine. This helps reduce excess fluid buildup in the body.

What are the ingredients in LASIX SPECIAL?

Medicinal ingredients: Furosemide

Non-medicinal ingredients:

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

LASIX SPECIAL comes in the following dosage forms:

Tablets: 500 mg

Do not use LASIX SPECIAL if:

- you are allergic to furosemide or any of the other ingredients in LASIX SPECIAL.
- you are allergic to sulfonamides, also known as “sulfa drugs”. Ask your healthcare professional if you are unsure.
- you have kidney failure. This includes if:
 - you have it due to taking substances or medicines that are known to cause kidney or liver damage.
 - it is accompanied by a decline in brain function, including coma, as a result of liver failure.
- you have severe kidney damage. Taking LASIX SPECIAL may cause extreme water and electrolyte losses. Your healthcare professional will carefully assess your kidney function and decide if you should take LASIX SPECIAL.
- you have cirrhosis of the liver (permanent damage or scarring of the liver).
- you have been told you have low electrolyte levels (such as sodium or potassium) in the blood.
- you are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- you have low blood volume.
- you have low blood pressure.
- you are below 15 years of age.
- you are breastfeeding or planning to breastfeed.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LASIX SPECIAL. Talk about any health conditions or problems you may have, including if you:

- are taking any of the following medicines:
 - digitalis glycosides, used to treat various heart conditions.

- risperidone, used to treat mental or mood disorders (e.g., schizophrenia, bipolar disorder). The combination of furosemide, the active ingredient in LASIX SPECIAL, and risperidone has been linked to a higher rate of death in elderly patient with dementia (loss of memory and other mental abilities).
- medicines used to reduce inflammation such as certain steroids, or glucocorticoids.
- medicines that are known to cause ear damage.

Ask your healthcare professional if you are unsure.

- have difficulty urinating.
- have lupus, or have had an episode of lupus (an autoimmune disease). LASIX SPECIAL may activate or worsen your condition.
- had or will have a kidney transplant.
- have been told you have low levels of protein, chloride, magnesium, or calcium in the blood.
- have high blood sugar or diabetes. LASIX SPECIAL may affect your blood sugar levels and accelerate the development of diabetes.
- intend to change your eating habits.
- have liver problems.
- have kidney problems, including hepatorenal syndrome (kidneys stop working well in people with serious liver problems).
- have high levels of uric acid in the blood, or have gout. LASIX SPECIAL may make a gout attack more likely.
- are planning to have surgery (including dental procedures).
- are at risk from a rapid fall in blood pressure (e.g., you have abnormal narrowing in the arteries that supply blood to your heart or brain).
- are pregnant, planning to become pregnant or think you might be pregnant.

Other warnings you should know about:

Diet: You should not be on a low-salt diet while taking LASIX SPECIAL. If you are taking LASIX SPECIAL for an extended period of time, your healthcare professional may recommend that you eat a diet rich in potassium. They may also recommend that you take potassium supplements, especially if you have been prescribed high doses of LASIX SPECIAL.

Hearing problems: LASIX SPECIAL may cause ringing in the ears, or temporary or permanent hearing loss.

Surgery: Tell any doctor, dentist, pharmacist or healthcare professional that you see, that you are taking this medicine. This is especially important if you are planning to have surgery (including dental procedures). Your healthcare professional may ask you to stop taking LASIX SPECIAL a week before your surgery. Follow their instructions carefully.

Pregnancy: It is not known if LASIX SPECIAL can harm an unborn baby. LASIX SPECIAL is not recommended during pregnancy or in women capable of becoming pregnant, unless your

healthcare professional decides the benefits outweigh the potential risks to your baby. If it is decided that you can take LASIX SPECIAL during pregnancy, your healthcare professional will closely monitor your health and that of your baby. If you discover that you are pregnant while taking LASIX SPECIAL, tell your healthcare professional **right away**.

Breast-feeding: LASIX SPECIAL passes into breast milk and may harm your baby. Do not breast-feed while you are taking LASIX SPECIAL. Talk to your healthcare professional about other ways to feed your baby during this time. Diuretics, such as LASIX SPECIAL, may also reduce the amount of breast milk you produce.

Driving and using machines: LASIX SPECIAL can cause low blood pressure or other side effects that may affect your abilities, especially at the start of your treatment. Before doing tasks that require special attention, wait until you know how you respond to LASIX SPECIAL.

Adults (over 61 years of age): Side effects like dehydration, low blood volume, blood circulation failure, and potentially blood clots are more likely. Your healthcare professional may adjust your dose of LASIX SPECIAL. They will monitor your health during your treatment.

Check-ups and testing: Your healthcare professional will do check-ups and tests while you are taking LASIX SPECIAL. These tests may include:

- blood tests to monitor:
 - the level of electrolytes (sodium, potassium, calcium, magnesium, or chloride) in your blood.
 - the level of carbon dioxide (CO₂) in your blood.
 - the level of sugar (glucose) in your blood.
 - the health of your blood, liver and kidneys.
- urine tests to monitor the level of sugar (glucose) in your urine.
- blood pressure checks to monitor your blood pressure.

Your healthcare professional will also:

- regularly monitor you for signs of electrolyte imbalances.
- monitor if you have problems urinating, especially when starting treatment with LASIX SPECIAL.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LASIX SPECIAL:

- other diuretics (also known as “water pills”), which are used to help rid your body of salt and water, such as hydrochlorothiazide, or ethacrynic acid.
- medicines used to treat high blood pressure such as enalapril, ramipril, lisinipril, irbesartan, valsartan, losartan, and aliskiren.
- medicines that raise your blood pressure such as epinephrine (used to treat life-threatening allergic reactions).
- medicines used to reduce inflammation such as certain steroids, or glucocorticoids.

- medicines used to relieve pain, fever and inflammation such as non-steroidal anti-inflammatory drugs (NSAIDs), including indomethacin, acetylsalicylic acid (ASA), or other salicylates.
- muscle relaxants used during surgery or other procedures such as tubocurarine, or curare.
- medicines used to treat seizures such as carbamazepine, phenobarbital, or phenytoin.
- medicines used to treat bacterial infections such as cefazolin, cefadroxil, or aminoglycosides.
- sedatives, which are used to treat insomnia, reduce anxiety, or help put you to sleep before surgery or other procedures such as chloral hydrate, or phenobarbital.
- digitalis glycosides, used to treat various heart conditions.
- methotrexate, used to treat cancer and certain autoimmune disorders.
- cisplatin, used to treat cancer.
- cyclosporine, used to suppress the immune system.
- levothyroxine, used to treat an underactive thyroid gland.
- probenecid, used to treat gout.
- risperidone, used to treat mental or mood disorders (e.g., schizophrenia, bipolar disorder).
- lithium, used to treat manic episodes of bipolar disorder.
- carbenoxolone, used to treat lip sores and mouth ulcers.
- sucralfate, used to treat and prevent ulcers in the intestines.
- theophylline, used to treat asthma and other breathing problems.
- radiocontrast agents, used during radiological examinations.
- medicines used to treat diabetes, including insulin, metformin, and glipizide.
- medicines that are known to cause ear or kidney damage.
- laxatives.
- licorice.

Ask your healthcare professional if you are not sure if a medicine you are taking is listed above.

How to take LASIX SPECIAL:

- Treatment with LASIX SPECIAL will be initiated in a hospital setting, under close observation with frequent blood tests to monitor electrolyte levels.
- Swallow tablets whole with a glass of water.
- Never increase or decrease your dose unless your healthcare professional tells you to.
- This medicine was specifically prescribed for you. Do not give it to others, even if they have the same symptoms. Do not use it for conditions other than the one for which it was prescribed.

Usual dose:

- Your healthcare professional will decide on the dose that is right for you, and when it should be taken depending on your condition. Take LASIX SPECIAL exactly as they tell you.
- The maximum daily dose is 1000 mg.

Overdose:

Signs of an overdose with LASIX SPECIAL may include:

- dehydration
- low electrolyte levels in the blood, which may cause you to feel weak, dizzy, confused, tired, have cramps or vomit.
- extremely low blood pressure that can lead to shock (rapid breathing, pale skin, cold and sweaty skin)
- a decline in brain function, including coma, in patients with liver problems (cirrhosis)
- severe kidney problems
- formation of one or more clots inside your blood vessels
- sudden change in mental status (delirium)
- sudden muscle weakness or paralysis (flaccid paralysis)
- lack of interest or emotions
- confusion

If you think you, or a person you are caring for, have taken too much LASIX SPECIAL, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

What are possible side effects from using LASIX SPECIAL?

These are not all the possible side effects you may have when taking LASIX SPECIAL. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- blurred or yellow vision
- indigestion, diarrhea, constipation
- sweet taste
- nausea or vomiting
- skin rash, hives, itchy skin, purple-coloured spots on the skin
- feeling like you are spinning (vertigo)

- feeling pressure in the head
- dizziness or feeling lightheaded
- headache
- fainting
- burning or prickling sensation in the hands, arms, legs, or feet

LASIX SPECIAL can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Dehydration: dry mouth, increased thirst, feeling tired or sleepy, lack of energy, passing less urine, headache, dizziness, low blood pressure, racing or irregular heart rate, fainting, confusion			✓
Electrolyte imbalance: dry mouth, feeling thirsty, feeling weak, lack of energy, drowsiness, restlessness, muscle pain or cramps, muscle fatigue, low blood pressure, irregular heartbeat, urinating less frequently, nausea, vomiting, high blood sugar			✓
COMMON			
Hypotension (low blood pressure): dizziness when rising to a standing position, impaired concentration and lightheadedness		✓	
Liver disorder: yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite, impaired brain function (trouble concentrating, confusion, reduced alertness, impaired		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
judgement), mood changes, muscle jerks, trouble sleeping, breath smells sweet and musty, disorientation			
Increased levels of uric acid in the blood: swelling, redness in the joints, sudden and intense attacks of joint pain (gout attack)		✓	
UNCOMMON			
Allergic reactions: sensitivity to light, tingling of fingers or toes, fever			✓
Hearing problems: ringing in the ears, deafness, both permanent and reversible		✓	
Serious skin reactions: raised red or purple skin patches, possibly with blister or crust in the center, possibly swollen lips, mild itching or burning; blisters of different sizes; skin redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, can be accompanied with fever, chills, headache, cough, body aches or swollen glands, yellow skin or eyes, shortness of breath, chest pain or discomfort, feeling thirsty, urinate less frequently			✓
VERY RARE			
Acute pancreatitis (inflammation of the pancreas): abdominal pain that radiates to your back, fever, rapid heart beat, nausea, vomiting,			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
tenderness when touching the abdomen			
UNKNOWN FREQUENCY			
Muscle problems: unexplained muscle pain, tenderness, weakness, cramps		✓	
Pseudo-Bartter syndrome (an acid-base and electrolyte imbalance): fatigue, muscle weakness, diarrhea, dehydration, increased thirst, increased urination, low blood pressure, irregular heartbeats			✓
Severe allergic reactions: sudden wheeziness and chest pain or tightness; or swelling of eyelids, face, lips, tongue or throat			✓
Thrombosis (clot in a blood vessel): pain, swelling tenderness in your leg or arm, warm, red skin and a heavy feeling in the affected area			✓
Kidney failure (severe kidney problems): weakness, trouble breathing, swelling, fast or irregular heartbeat, confusion, decrease or inability to urinate, loss of appetite, coma and death			✓
Increased blood sugar: frequent urination, thirst and hunger		✓	
Worsening or activation of lupus: fatigue, fever, joint pain, stiffness and swelling, rash on the face that covers the cheeks and the bridge of the nose or rashes elsewhere on the body, skin lesions, shortness of		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
breath, chest pain, dry eyes, headaches, confusion and memory loss			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.

Storage:

- Store your tablets at room temperature (15°C – 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 your healthcare professional tells you to keep them at home.
- Keep out of reach and sight of children.

If you want more information about LASIX SPECIAL:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofi.ca, or by calling 1-800-265-7927.

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