

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrLASIX® ORAL SOLUTION

Furosemide oral solution

Read this carefully before you start taking **LASIX ORAL SOLUTION** 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 ORAL SOLUTION**.

Serious Warnings and Precautions

- LASIX ORAL SOLUTION is a strong diuretic. Taking too much LASIX ORAL SOLUTION 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 ORAL SOLUTION 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 ORAL SOLUTION used for?

LASIX ORAL SOLUTION is used in adults and children:

- to treat swelling in the body caused by excess fluid in the tissues (edema) due to a medical condition. This may include congestive heart failure, liver disease (cirrhosis), kidney disease, including nephrotic syndrome, or other medical conditions.
- alone to treat mild to moderate high blood pressure.
- in combination with other medicines to treat severe high blood pressure.

How does LASIX ORAL SOLUTION work?

LASIX ORAL SOLUTION 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 swelling in the body and lower blood pressure.

What are the ingredients in LASIX ORAL SOLUTION?

Medicinal ingredients: Furosemide

Non-medicinal ingredients: Alcohol, butylated hydroxyanisole, butylated hydroxytoluene, glycerine, methylparaben, natural orange flavour, polysorbate 80, potassium sorbate, purified water, sodium hydroxide and sorbitol

LASIX ORAL SOLUTION comes in the following dosage forms:

Oral solution: 10 mg/mL

Do not use LASIX ORAL SOLUTION if:

- you are allergic to furosemide or any of the other ingredients in LASIX ORAL SOLUTION.
- you are allergic to sulfonamides, also known as “sulfa drugs”. Ask your healthcare professional if you are unsure.
- your kidneys have completely stopped working.
- you have severe liver disease or have a decline in brain function, including coma, as a result of liver failure.
- you have been told you have low levels of electrolytes (salts such as sodium, potassium, calcium, magnesium, or chloride) in the blood.
- you are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- you have low blood volume.
- you have low blood pressure.
- your newborn infant has jaundice (yellowing of the skin or whites of eyes), or your infant suffers from a disease that has the potential of causing a build-up of bilirubin in the blood, which can even lead to a type of brain damage called kernicterus. This includes diseases such as Rh incompatibility, familial non-hemolytic jaundice, etc. Your child’s healthcare professional will carefully assess their condition and decide if they should take LASIX ORAL SOLUTION.
- you are breastfeeding or planning to breastfeed.

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

- 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 ORAL SOLUTION, 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).
- had or will have a kidney transplant.

- have been told you have low levels of protein in the blood.
- have high blood sugar or diabetes. LASIX ORAL SOLUTION may affect your blood sugar levels and accelerate the development of diabetes.
- intend to change your eating habits.
- have liver problems, including cirrhosis of the liver (permanent damage or scarring of the liver).
- have ascites (collection of fluid in spaces within your abdomen due to a medical condition).
- 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 ORAL SOLUTION may make a gout attack more likely.
- was born prematurely (children).
- 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 ORAL SOLUTION. If you are taking LASIX ORAL SOLUTION 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 ORAL SOLUTION.

Hearing problems: LASIX ORAL SOLUTION may cause ringing in the ears, or temporary or permanent hearing loss, especially in children. In some cases, the onset of deafness was subtle at first but gradually worsened up to 6 months after treatment.

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 ORAL SOLUTION a week before surgery. Follow their instructions carefully.

Pregnancy: It is not known if LASIX ORAL SOLUTION can harm an unborn baby. LASIX ORAL SOLUTION 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 should take LASIX ORAL SOLUTION 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 ORAL SOLUTION, tell your healthcare professional **right away**.

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

Driving and using machines: LASIX ORAL SOLUTION 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 ORAL SOLUTION.

Infants and premature babies: If LASIX ORAL SOLUTION is given to infants or premature babies, they may be at higher risk for certain serious side effects. These include:

- **low blood calcium levels in infants**, which can lead to tetany. Tetany involves involuntary contraction of muscles, which leads to painful muscle spasms and stiff immovable muscles.
- **kidney stones in premature babies.**
- **a heart defect in premature babies whose lungs are not fully developed** when LASIX ORAL SOLUTION is given to them in their first few weeks of life.

See the **Serious side effects and what to do about them** table for more information on these and other serious side effects.

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 ORAL SOLUTION and monitor your health closely during treatment.

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

- blood tests to monitor:
 - the level of electrolytes (sodium, potassium, calcium, magnesium, or chloride) in the blood.
 - the level of carbon dioxide (CO₂) in the blood.
 - the level of sugar (glucose) in the 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 ORAL SOLUTION.

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

The following may interact with LASIX ORAL SOLUTION:

- 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 or your child are taking is listed above.

How to take LASIX ORAL SOLUTION:

- Your or your child's healthcare professional will decide on the dose that is right for you or your child, and when it should be taken depending on your or your child's condition. Take LASIX ORAL SOLUTION exactly as they tell you.
- Never increase or decrease your or your child's dose unless your healthcare professional tells you to.
- LASIX ORAL SOLUTION should be taken on an empty stomach.
- In children, treatment with LASIX ORAL SOLUTION will be initiated in a hospital setting, under close observation with frequent blood tests to monitor electrolyte levels.
- This medicine was specifically prescribed for you or a child in your care. 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:**Adults:**

- To treat swelling: The usual dose is 4mL to 8mL of 10 mg/mL mg, taken 1 to 3 times a day. Your healthcare professional may adjust your dose depending on how you respond to LASIX ORAL SOLUTION. The maximum daily dose is 20 mL of 10 mg/mL.
- To treat high blood pressure: The usual dose is 2 mL to 4 mL of 10 mg/mL, twice daily.

Children:

- Your child's healthcare professional will determine the right dose based on your child's weight. Follow their instructions carefully.
- The usual starting dose for children is 0.5 to 1 mg for each kg they weigh in divided doses, 6 to 12 hours apart. The maximum daily dose is 2 mg for each kg they weigh. In newborn and premature babies, the maximum daily dose is 1 mg for each kg they weigh.

Overdose:

Signs of an overdose with LASIX ORAL SOLUTION 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 ORAL SOLUTION, 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 ORAL SOLUTION?

These are not all the possible side effects you may have when taking LASIX ORAL SOLUTION. 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 ORAL SOLUTION 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,			✓

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	
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 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			✓

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	
Hearing problems: ringing in the ears, deafness, sometimes non-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, 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			✓

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	
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			✓
Heart defect in premature babies whose lungs are not fully developed: fast breathing or shortness of breath, rapid heart rate, heart murmur, trouble feeding leading to poor weight gain, sweating when eating or crying, tires easily when eating or playing		✓	
Low blood calcium levels in infants: floppy muscles, fast heart rate, rapid breathing, trouble feeding leading to poor weight gain, jitteriness, seizures, involuntary muscle contractions and stiff immovable muscles (tetany).		✓	
Kidney stones in premature babies: blood in the urine, fever and chills, nausea and vomiting, sharp pain in back or side, constant need to urinate, pain		✓	

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	
while urinating, inability to urinate or can urinate only a small amount, cloudy or bad smelling urine			
Increased blood sugar: frequent urination, thirst and hunger		✓	
Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine			✓
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 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 solution at room temperature (15°C – 30°C). Protect from light.
- There is an expiration date on the label. Do not use the medicine after this date.
- Return any leftover solution 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 ORAL SOLUTION:

- 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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