

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **LOKELMA®**

sodium zirconium cyclosilicate powder for oral suspension

This Patient Medication Information is written for the person who will be taking **LOKELMA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **LOKELMA**, talk to a healthcare professional.

What LOKELMA is used for:

LOKELMA is used to treat hyperkalemia in adults. Hyperkalemia means that there is a high level of potassium in the blood.

How LOKELMA works:

LOKELMA lowers the high levels of potassium in your body and helps to keep it at a normal level. As LOKELMA passes through your stomach and gut it binds to potassium. The two are then carried together out of the body in your stools. This lowers the amount of potassium in the body.

LOKELMA starts to lower your potassium within one hour of taking it. The amount of decrease depends on your starting potassium level. Most patients have normal levels within 24 to 48 hours of treatment.

The ingredients in LOKELMA are:

Medicinal ingredient: sodium zirconium cyclosilicate

Non-medicinal ingredients: None

LOKELMA comes in the following dosage form:

Powder for oral suspension in sachets of 5 g and 10 g.

Each 5 g of sodium zirconium cyclosilicate contains about 400 mg of sodium.

Do not use LOKELMA if:

- you are hypersensitive or allergic to the ingredient sodium zirconium cyclosilicate.

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

- are pregnant or planning to become pregnant;
- have any existing heart rhythm problems;
- are reducing how much salt (sodium) you eat. LOKELMA contains about 400 mg of sodium per 5 g;
- have a history of heart failure or kidney disease, especially if your body is prone to retaining too much water, or if the amount of sodium in your diet is not well controlled.

- have severe constipation, a bowel obstruction or a bowel motility disorder.

Other warnings you should know about:

Monitoring: Your healthcare professional will check your blood potassium level when you start taking this medicine and during your treatment.

- This is to make sure you are getting the correct dose. The dose may be raised or lowered based on your blood potassium level.
- Treatment may be stopped if your blood potassium becomes too low.
- Tell your healthcare professional if you are taking, starting, stopping or changing your dose of any medicines which can change your blood potassium levels because your dose of LOKELMA may need to be changed. These types of medicines include:
 - Medicines that increase urine production (diuretics)
 - Medicines used to treat high blood pressure and heart problems

Worsening of pre-existing heart failure: Talk to your healthcare professional before taking LOKELMA if you have a history of heart failure as it may make your condition worse.

Signs and symptoms of worsening heart failure include:

- Shortness of breath that gets worse
- Swelling of your legs or ankles
- Sudden weight gain

If you experience any of these signs and symptoms, contact your healthcare professional immediately.

X-rays: Tell your healthcare professional if you need to have an abdominal X-ray. LOKELMA may affect the interpretation of the results.

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 LOKELMA:

LOKELMA may affect how certain other medicines are absorbed from your digestive tract. If you take any of the following medicines, you may need to take LOKELMA at least 2 hours before or 2 hours after taking any of them, otherwise they may not work properly:

- atorvastatin, used to lower cholesterol;
- medicines used to treat fungal infections such as ketoconazole, itraconazole, and posaconazole;
- medicines used to prevent and treat HIV/AIDS such as atazanavir, nelfinavir, indinavir, ritonavir, saquinavir, and raltegravir;
- medicines used to treat certain types of cancer such as erlotinib, dasatinib, and nilotinib;
- dabigatran, used to thin the blood;
- tacrolimus, used to suppress your body's immune system to prevent organ transplant rejection.

How to take LOKELMA:

- Always take this medicine exactly as your healthcare professional has told you. Check with your healthcare professional or pharmacist if you are not sure.
- Try to take LOKELMA at the same time each day.
- You can take this medicine with or without food.

- Before opening the sachets, hold the top corner of the sachet and shake it to move the powder to the bottom.
- Open the sachet and pour the powder into a glass with approximately 45 mL (3 tablespoons) of water.
- Stir well and drink the tasteless liquid right away before the powder settles.
- The powder does not dissolve and the liquid will appear cloudy. The white to grey powder will settle in the glass quickly. If this happens, stir the liquid again and drink it all up.
- If needed, add a little more water to the glass. Swirl and drink it to take all the medicine.

Usual dose:

Correction dose - to lower your high potassium level to normal:

- The recommended dose is 10 g taken three times a day.
- The medicine takes one to two days to work.

Maintenance dose - to keep your potassium level within the normal range after it has been lowered:

- The recommended dose is 5 g taken once a day.
- Your healthcare professional may decide that you need more (10 g once a day) or less (5 g every other day).
- Do not take a maintenance dose of more than 10 g once a day.

Dosing **only** for patients on hemodialysis therapy:

- Take LOKELMA only on non-dialysis days.
- The recommended starting dose is 5 g taken once a day.
- Your healthcare professional may decide that you need more (up to 15 g once a day) or that you need to stop for a few days.
- If your healthcare professional recommends a 15 g dose, you will need to use a 5 g sachet and a 10 g sachet to make a 15 g dose. If you are taking 15 g, you still need to use approximately 45 mL (3 tablespoons) of water.
- Do not take more than 15 g once a day.

Do not reduce the dose of this medicine or stop taking it without talking to the healthcare professional. This is because your blood potassium levels may rise again.

Overdose:

If you think you, or a person you are caring for, have taken too much LOKELMA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

- If you forget to take a dose of this medicine, skip the missed dose.
- Then take the next dose as usual at your normal time.
- Do not take a double dose to make up for the missed dose.

Possible side effects from using LOKELMA:

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

Side effects with LOKELMA may include:

- **Hypokalemia** (low level of potassium in the blood): fatigue, or have muscle weakness or cramps.
- **Hypomagnesemia** (low level of magnesium in the blood): abnormal eye movements, fatigue, muscle spasms or cramps, muscle weakness, numbness.
- Muscle spasms.
- **Gastroenteritis** (inflammation of the stomach and intestines) **or other gastrointestinal disorders**: constipation, diarrhea, nausea, abdominal pain, vomiting.
- **Hypocalcemia** (low calcium levels in the blood): confusion or memory loss, muscle spasms, numbness and tingling in the hands, feet and face, muscle cramps, weak and brittle nails.

Serious side effects and what to do about them

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very Common			
Worsening of Pre-Existing Heart Failure (heart does not pump blood as well as it should): shortness of breath that gets worse, swelling in ankles and legs, sudden weight gain.		✓	
Common			
Constipation	✓		
Edema (a build up of fluid in the tissues): swelling anywhere in the body, usually in the ankles and feet.		✓	
Uncommon			
Prolongation of QT interval (a heart rhythm condition): irregular heartbeat, fainting, loss of consciousness, seizures.		✓	
Congestive Heart Failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise.		✓	

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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

- Store LOKELMA at 15-30°C.
- Keep out of reach and sight of children.
- Do not use this medicine after the expiry date stated on the carton and the sachet after 'EXP'. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If you want more information about LOKELMA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.astrazeneca.ca; or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

This leaflet was prepared by AstraZeneca Canada Inc., Mississauga, Ontario L4Y 1M4.

Date of Authorization: 2026-03-24

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