



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

LOKELMA™

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking LOKELMA?

LOKELMA contains the active ingredients sodium zirconium cyclosilicate hydrate. LOKELMA is used to treat hyperkalaemia in adults.

For more information, see Section [1. Why am I taking LOKELMA?](#) in the full CMI.

2. What should I know before I take LOKELMA?

Do not use if you have low blood potassium levels or if you are pregnant

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take LOKELMA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LOKELMA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take LOKELMA?

- Your Doctor will tell you how to take LOKELMA and how often you should take them.
- LOKELMA can be taken with or without a meal.

More instructions can be found in Section [4. How do I take LOKELMA?](#) in the full CMI.

5. What should I know while taking LOKELMA?

Things you should do	• Talk to your doctor if you need to have an X-ray • Talk to your doctor if you become pregnant • Talk to your doctor if you have heart failure. In some patients, this medicine may make this condition worse
Things you should not do	• Do not stop taking your medicine or change the dosage without checking with your doctor.
Driving or using machines	• LOKELMA is unlikely to affect your ability to drive or to use machines.
Looking after your medicine	• LOKELMA is a white to grey, crystalline, insoluble powder. It comes in a sachet. • This medicine does not require any special storage conditions.

For more information, see Section [5. What should I know while taking LOKELMA?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, some can be minor and temporary. However, some side effects may be serious and could require urgent medical attention or hospitalisation. See Section [6. Are there any side effects?](#) in the full CMI and, if you need to, ask your doctor if you have any further questions about side effects. Tell your doctor if you experience any side effects, including those not listed in this leaflet.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

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LOKELMA™

Active ingredient(s): sodium zirconium cyclosilicate hydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about taking LOKELMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking LOKELMA.**

Where to find information in this leaflet:

1. [Why am I taking LOKELMA?](#)
2. [What should I know before I take LOKELMA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take LOKELMA?](#)
5. [What should I know while taking LOKELMA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking LOKELMA?

LOKELMA contains the active sodium zirconium cyclosilicate.

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

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 attaches to potassium and the two are carried together out of the body in your stools, lowering the amount of potassium in the body.

2. What should I know before I take LOKELMA?

Warnings

Your doctor or nurse will check your blood potassium level when you start taking medicine to ensure to get the correct dose. The dose may be raised or lowered based on your blood potassium level. Treatment may be stopped if your blood potassium level becomes too low.

Do not take LOKELMA if you:

- Are under 18 years of age as effects of LOKELMA in children and adolescents are not known
- If you are pregnant, think you may be pregnant or you are planning to have a baby, tell your doctor
- If you are allergic to sodium zirconium cyclosilicate

Check with your doctor if you:

- Need to have X-ray as LOKELMA may affect the interpretation of results
- Are taking any medicines which may change your blood potassium levels because your dose of LOKELMA may need to be changed. These include diuretics (medicines that increase urine production), angiotensin converting enzyme (ACE) inhibitors such as enalapril, angiotensin receptor blockers such as valsartan (medicines for high blood pressure and for heart problems), and renin inhibitors such as aliskiren (for high blood pressure).
- Have a heart signaling disorder (QT prolongation) since LOKELMA lowers your blood potassium levels, which may affect heart signaling
- Have heart failure. In certain patients, this medicine may make your condition worse. Signs and symptoms of worsening heart failure include:
 - o Worsening of current shortness of breath
 - o Swelling of legs or ankles
 - o Sudden weight gain

Talk to your doctor immediately if you experience any of these symptoms.

- During treatment, you may be at risk of developing certain
- side effects. It is important you understand these risks and
- how to monitor for them. See additional information
- under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take LOKELMA if you are pregnant, think you may be pregnant or plan to become pregnant.

No effects on the breastfed newborn/infant are anticipated since LOKELMA is not systemically absorbed and is not expected to be passed into your breast milk. Tell your doctor if you are breastfeeding or plan to breastfeed.

Children

Do not give this medicine to children and adolescents under 18 years of age.

This is because the effects of LOKELMA in children and adolescents are not known.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

LOKELMA may affect how certain medicines are absorbed from your digestive tract. If you are taking any of the following medicines, they should be taken 2 hours before or after taking LOKELMA, otherwise they may not work properly.

- Tacrolimus (medicines used to suppress your body's immune system to prevent organ transplant rejection)
- Ketoconazole, itraconazole and Posaconazole (used to treat fungal infections)
- Atazanavir, nelfinavir, indinavir, ritonavir, saquinavir, raltegravir, ledipasvir and rilpivirine (used to treat HIV infection)
- Tyrosin kinase inhibitors, such as erlotinib, dasatinib and nilotinib (used to treat cancer)

If you are taking lithium-based medicines, they should be taken 3 hours before or after taking LOKELMA to make sure that they work properly.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LOKELMA.

4. How do I take LOKELMA?

How to take LOKELMA

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

- Open the sachet(s) and pour the powder into a drinking glass with approximately 45 mL of still (non-carbonated) water.
- Stir well and drink the tasteless liquid straight away.
- The powder does not dissolve and the liquid appears 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, rinse the glass with a small amount of water and drink it up to take all the medicine.

Starting 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.
- Do not take this starting dose for more than three days.

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 doctor may decide that you need more (10 g once a day) or less than this (5 g every other day).
- Do not take more than 10 g once a day.

If you are on haemodialysis therapy:

- Take LOKELMA only on non-dialysis days.
- The recommended starting dose is 5 g taken once a day.
- Your doctor may decide that you need more (up to 15 g once a day).
- Do not take more than 15 g once a day.

When to take LOKELMA

- **Try to take LOKELMA at the same time each day.**
- You can take this medicine with or without a meal.

How long to take

- **Continue taking your medicine for as long as your doctor tells you**

If you forget to take LOKELMA

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much LOKELMA

If you think that you have used too much LOKELMA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking LOKELMA?

Things you should do

Talk to your doctor if you need to have an X-ray, LOKELMA may affect the interpretation of results.

If you become pregnant while taking LOKELMA, tell your doctor immediately.

Things you should not do

- Do not stop taking your medicine or change the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LOKELMA affects you.

LOKELMA is unlikely to affect your ability to drive or to use machines.

Looking after your medicine

- Do not use this medicine after the expiry date which is stated on the carton and the sachet after 'EXP'. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Do not use any pack that is damaged or shows signs of tampering.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Muscle-related (may be a sign of low blood potassium levels): • muscle weakness, tiredness • muscle cramps Others: • swelling in feet and ankles • fluid built up in tissues • constipation	Speak to your doctor if you have any of these less serious side effects or if the symptoms become severe and they worry you.

Serious side effects

Serious side effects	What to do
Heart-related: • Worsening of pre-existing heart failure	Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LOKELMA contains

Active ingredient (main ingredient)	• Sodium zirconium cyclosilicate hydrate 5 mg • Sodium zirconium cyclosilicate hydrate 10 mg
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Do not take this medicine if you are allergic to any of these ingredients.

What LOKELMA looks like

LOKELMA is a white to grey, crystalline, insoluble powder. It comes in a sachet.

- LOKELMA 5 g powder for oral suspension contains 5 g sodium zirconium cyclosilicate hydrate
- LOKELMA 10 g powder for oral suspension contains 10 g sodium zirconium cyclosilicate hydrate

Who distributes LOKELMA

AstraZeneca Pty Ltd
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66 Talavera Road
MACQUARIE PARK NSW 2113
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