Package Leaflet: Information for the patient

Lokelma® 5 g powder for oral suspension
Lokelma® 10 g powder for oral suspension
sodium zirconium cyclosilicate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lokelma is and what it is used for

Lokelma contains the active substance 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 you need to know before you take Lokelma

Do not take Lokelma
- If you are allergic to the active substance.

Warnings and precautions
Monitoring
Your doctor or nurse will check your blood potassium level when you start taking this medicine:
- 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 level becomes too low.
- Tell your doctor or nurse if you are taking any medicines which can 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).

While you are taking Lokelma, tell your doctor or nurse if

- you have a heart signalling disorder (QT prolongation) since Lokelma lowers your blood potassium levels which may affect heart signalling.
- you need to have an X-ray, as Lokelma may affect the interpretation of the results.
- you have sudden or severe pain in your abdomen as this may be a sign of a problem that is observed with medicines that work in the gastrointestinal tract.

Children and adolescents
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.

Other medicines and Lokelma
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

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)
- tyrosine kinase inhibitors such as erlotinib, dasatinib and nilotinib (used to treat cancer)

If any of the above apply to you (or you are not sure), tell your doctor, pharmacist or nurse before taking this medicine.

Pregnancy and breast feeding
Pregnancy
Do not use this medicine during pregnancy because there is no information on its use in pregnancy.

Breast-feeding
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Lokelma is negligible. Lokelma can be used during breast-feeding.

Driving and using machines
This medicine has no or negligible influence on your ability to drive or to use machines.

Lokelma contains sodium
This medicine contains approximately 400 mg sodium (main component of cooking/table salt) in each 5 g dose. This is equivalent to 20% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your pharmacist or doctor if you need Lokelma 5 g or more daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. 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
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 a maintenance dose of 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.

Taking this medicine
- Try to take Lokelma at the same time each day.
- You can take this medicine with or without meal.

How 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 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 all up to take all the medicine.

If you take more Lokelma than you should:
If you take more of this medicine than you should, talk to a doctor straight away. Do not take any more until you have spoken to a doctor.

If you forget to take Lokelma
- 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 a forgotten dose.

If you stop taking Lokelma
Do not reduce the dose of this medicine or stop taking it without talking to the doctor who prescribed it. This is because you may get high potassium levels in your blood again.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or nurse if you experience any of the following:
Common side effects (may affect up to 1 in 10 people).
- you start to feel tired, or have muscle weakness or cramps, this may be a sign that your blood potassium has become too low. Talk to your doctor immediately if these symptoms become severe.
- you start to have a build up of fluid in the tissues, leading to swelling anywhere in your body (usually in the feet and ankles).
- constipation.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lokelma

Keep this medicine out of the sight and reach of children.

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 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.

6. Contents of the pack and other information

What Lokelma contains
The active substance is sodium zirconium cyclosilicate.

Lokelma 5 g powder for oral suspension
Each sachet contains 5 g of sodium zirconium cyclosilicate.

Lokelma 10 g powder for oral suspension
Each sachet contains 10 g of sodium zirconium cyclosilicate.

There are no other ingredients in this medicine.

What Lokelma looks like and contents of the pack
The powder for oral suspension is a white to grey powder. It comes in a sachet.

Lokelma 5 g powder for oral suspension
Each sachet contains 5 g of powder.

Lokelma 10 g powder for oral suspension
Each sachet contains 10 g of powder.

The sachets are supplied in a carton containing 3 or 30 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

AstraZeneca UK Limited,
1 Francis Crick Avenue,
Cambridge,
CB2 0AA,
UK.

Manufacturer

AstraZeneca AB
Gärtunavägen
SE-152 57 Södertälje
Sweden

This leaflet was last revised in 03/2024

CV 24 0023

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	**Reference number**
Lokelma 5 g powder for oral suspension	17901/0332
Lokelma 10 g powder for oral suspension	17901/0331

This is a service provided by the Royal National Institute of the Blind.