

LOKELMA[®] POWDER FOR ORAL SUSPENSION

Sodium zirconium cyclosilicate (5 g, 10 g)

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What Lokelma is used for

Lokelma is used to treat hyperkalaemia in adults. Hyperkalaemia 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 attaches to potassium and the two are carried together out of the body in your stools, lowering the amount of potassium in the body.

Before you use Lokelma

- When you must not use it

Do not take this medicine if you are allergic to the active substance.

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.

- Before you start to use it

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).

- Taking other medicines

Tell your doctor or pharmacist 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)

How to use 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 use

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 or two days to work.
- Do not take this starting dose for more than three days.

Maintenance dose – to keep your potassium level within 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.

- When to use it

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

- 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 all up to take all the medicine.

- How long to use it

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.

- If you forget to use it

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 use too much (overdose)

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.

While you are using Lokelma

- Things you must do

While taking Lokelma, tell your doctor if:

- you have a heart signaling disorder (QT prolongation) since Lokelma lowers your blood potassium levels which may affect heart signaling.
- 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.
- you have pre-existing heart failure. In certain patients, this

medicine may make this condition worse. Signs and symptoms of worsening heart failure may 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 doctor immediately.

- Things you must not do

Do not stop taking this medicine. Talk to your doctor first. It is important to take this medicine every day, for as long as your doctor prescribes it for you.

- Things to be careful of

Pregnancy

If you are pregnant, think you may be pregnant, or you are planning to have a baby, tell your doctor.

Breast-feeding

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.

Driving and using machines

Lokelma is unlikely to affect 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.

Side effects

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

Tell your doctor or pharmacist if you experience any of the following:

Very Common side effects (may affect more than 1 in 10 people):

- Worsening of pre-existing heart failure.

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.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Lokelma

- Storage

- 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.
- Store below 30°C.
- Do not use any pack that is damaged or shows signs of tampering.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Lokelma is a white to grey, crystalline, insoluble 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.

Lokelma is supplied in a carton containing 3 or 30 sachets. Not all package sizes may be marketed.

- Ingredients

- Active ingredient
 - Sodium zirconium cyclosilicate

- Inactive ingredients
There are no other ingredients in this medicine.

- MAL number:

5 g: MAL23026001ACZ

10 g: MAL23026002ACZ

Manufacturer

AndersonBrecon Inc.
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Product Registration Holder

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