Patient Package Insert in Accordance with the Pharmacists' Regulations (Preparations) – 1986

The medicine is dispensed with a doctor's prescription only

Lokelma® 5 g

Powder for oral suspension

Each sachet contains:
Sodium zirconium cyclosilicate 5 g

Lokelma® 10 g

Powder for oral suspension

Each sachet contains:
Sodium zirconium cyclosilicate 10 g

This medicine contains sodium, please see section 2: "Important information regarding some of the medicine ingredients".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Lokelma is indicated for the treatment of hyperkalaemia in adult patients.
Hyperkalaemia means that there is a high level of potassium in the blood.

Therapeutic group

Drugs for treatment of hyperkalaemia and hyperphosphatemia.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- you are hypersensitive (allergic) to the active substance contained in the medicine.

Special warnings regarding the use of Lokelma

Monitoring

Your doctor or nurse will check your blood potassium level before 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 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.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age. This is because there is no information regarding the safety and efficacy for use of this medicine in children and adolescents.

Tests and follow-up

Your doctor or nurse will check your blood potassium level before you start taking this medicine.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

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 2 hours 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 breastfeeding

Pregnancy

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

Breastfeeding

No effects on the breastfed infant are anticipated since the systemic exposure of the breastfeeding woman to Lokelma is negligible. Lokelma can be used during breastfeeding.

Driving and operating machinery

Lokelma has no or negligible influence on your ability to drive or to use machines.

Important information regarding some of the medicine ingredients

Lokelma contains sodium

This medicine contains approximately 400 mg sodium (the 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 doctor or pharmacist 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 SHOULD YOU USE THE MEDICINE?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with this medicine.

The dosage and manner of treatment will be determined only by your doctor. The usual dose is generally:

Starting dose - to lower the high potassium level to normal:

- The recommended dose is 10 g taken 3 times a day.
- The medicine takes one to two days to work.
- Do not take this starting dose for more than 3 days.

Maintenance dose - to keep the potassium level within the normal range after the potassium level 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.

Do not exceed the recommended dosage.

Manner of use

- Try to take Lokelma at the same time each day.
- You can take this medicine with or without food.
- 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 have accidentally taken a higher dose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not take another dose until you have spoken to a doctor.

If you forgot to take the medicine

- If you forgot to take this medicine at the scheduled time, skip the missed dose.

- Take the next dose as usual at your normal time.
- Do not take a double dose to make up for a forgotten dose.
- Adhere to the treatment regimen as recommended by your doctor.

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.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

As with any medicine, using Lokelma may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Common side effects - effects occurring in 1-10 of 100 users:

- 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.

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW SHOULD LOKELMA BE STORED?

- Avoid Poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at or below 30°C.

6. FURTHER INFORMATION

The medicine solely contains the active substance, without any other ingredients.

What does the medicine look like and the content 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.

Each carton contains 3 or 30 sachets. Not all pack sizes may be marketed.

Manufacturer:

AstraZeneca Pharmaceuticals LP, Texas, USA.

License holder:

AstraZeneca (Israel) Ltd.,
1 Atirei Yeda St., Kfar Saba 4464301.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Lokelma 5 g: 166-84-36547-99
Lokelma 10 g: 166-85-36548-99

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