

PRESCRIBING INFORMATION

LOKELMA® (sodium zirconium cyclosilicate) 5g & 10g POWDER FOR ORAL SUSPENSION

Consult Summary of Product Characteristics before prescribing.

**Indication:** Lokelma is indicated for treatment of hyperkalaemia in adults.

**Presentation:** 5g or 10g powder for oral suspension. Each sachet contains 5g or 10g sodium zirconium cyclosilicate.

**Dosage and Administration:** **Correction phase:** Recommended starting dose is 10g, administered orally, three times a day as a suspension in water. When normokalaemia is achieved the maintenance regimen should be followed. Typically, normokalaemia is achieved within 24 to 48 hours. If patient is still hyperkalaemic after 48 hours of treatment the same regimen can be continued for an additional 24 hours. If normokalaemia not achieved after 72 hours of treatment, other treatment options should be considered. **Maintenance phase:** Establish the minimal effective dose to prevent recurrence of hyperkalaemia. Recommended starting dose of 5g once daily, with possible titration up to 10g once daily, or down to 5g once every other day, as needed, to maintain normal potassium level. No more than 10g once daily should be used for maintenance therapy. Monitor serum potassium levels regularly during treatment. **Missed dose:** If a dose is missed the patient should take the next usual dose at their normal time. **Renal impairment:** No dosage adjustment required for patients who are not on chronic haemodialysis. For patients on dialysis Lokelma should only be dosed on non-dialysis days. The recommended starting dose is 5g once daily. To establish normokalaemia (4.0-5.0 mmol/L), the dose may be titrated up or down weekly based on the pre-dialysis serum potassium value after the long inter-dialytic interval (LIDI). The dose could be adjusted at intervals of one week in increments of 5g up to 15g once daily on non-dialysis days. It is recommended to monitor serum potassium weekly while the dose is adjusted; once normokalaemia is established, potassium should be monitored regularly (e.g. monthly, or more frequently based on clinical judgement including changes in dietary potassium or medication affecting serum potassium). **Hepatic impairment:** No changes from the normal doses are required for patients with hepatic impairment. **Elderly population:** No special dose and administration guidelines are recommended for this population. **Paediatric population:** Safety and efficacy has not been established in children and adolescents (<18 years). **Method of administration:** The entire contents of the sachet(s) should be emptied in a drinking glass containing approximately 45ml of water and stirred well. The tasteless liquid should be drunk while still cloudy. The powder will not dissolve. If the powder settles, the liquid should be stirred again and taken. If needed, rinse the glass with more water to ensure that all of the content is taken. The suspension can be taken with or without food.

**Contraindications:** Hypersensitivity to the active substance.

**Warnings and Precautions:** Serum potassium levels: Monitor serum potassium levels when clinically indicated, including after changes are made to medicinal products that affect the serum potassium concentration (e.g. renin-angiotensin-aldosterone system (RAAS) inhibitors or diuretics) and after Lokelma dose is titrated. Monitoring frequency will depend upon a variety of factors including other medicinal products, progression of chronic kidney disease and dietary potassium intake. **Hypokalaemia:** Hypokalaemia may be observed. To prevent moderate to severe hypokalaemia dose titration (maintenance posology) may be required. Discontinue and re-evaluate treatment in patients with severe hypokalaemia. **Worsening of pre-existing heart failure:** Monitor patients with pre-existing heart failure, particularly those in whom an increased sodium intake may lead to fluid

overload and decompensation. Manifestations of worsening heart failure, including increased dyspnoea, oedema and rapid weight gain, should be managed as per standard clinical practice. **QT Prolongation:** During correction phase, a lengthening of QT interval can be observed as the physiologic result of decline in serum potassium concentration. **Risk of interaction with X rays:** Sodium zirconium cyclosilicate may be opaque to X-rays, keep in mind if patient has abdominal X-ray. **Intestinal perforation:** Risk of intestinal perforation unknown. Special attention to be paid as intestinal perforation has been reported with potassium binders including Lokelma. **Sodium content:** Lokelma is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

**Drug Interactions:** No expected effects of other medicines on sodium zirconium cyclosilicate as it is not absorbed or metabolised by the body. Sodium zirconium cyclosilicate can transiently increase gastric pH and can lead to changes in solubility where co-administered medicinal product has pH-dependent stability and therefore should be administered at least 2 hours before or 2 hours after oral medicinal products with clinically meaningful gastric pH dependent bioavailability (e.g. azole antifungals, a number of anti-HIV agents, and tyrosine kinase inhibitors). Sodium zirconium cyclosilicate can be co-administered without spacing of dosing times with oral medicinal products that do not exhibit pH-dependent bioavailability. Tacrolimus should be taken at least 2 hours before or after Lokelma.

**Pregnancy and Lactation:** Preferable to avoid use during pregnancy. Can be used during breast-feeding.

**Ability to Drive and Use Machines:** Lokelma has no or negligible influence on the ability to drive and use machines.

**Undesirable Events: Consult SmPC for full list of side effects. Very Common:** Worsening of pre-existing heart failure (including increased dyspnoea, oedema and rapid weight gain). **Common:** Hypokalaemia, constipation, oedema related events (including fluid retention, generalised oedema, hypervolaemia, localised oedema, oedema, oedema peripheral, peripheral swelling).

**Legal Category:** POM.

**Marketing Authorisation Numbers:** PLGB 17901/0332, PLGB 17901/0331.

**Presentation & Basic NHS Cost:** 5g x 30 pack: £156; 10g x 3 pack: £31.20; 10g x 30 pack: £312.

**Business Responsible for Sale and Supply / Further Information:** AstraZeneca UK Ltd., 2 Pancras Square, 8th Floor, London, N1C 4AG, UK.

LOKELMA is a trade mark of the AstraZeneca group of companies.

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CV 26 0002

**Abbreviations:** CKD=chronic kidney disease; HF=heart failure; RAASI=renin-angiotensin-aldosterone system inhibitor.

**References:** 1. LOKELMA® Summary of Product Characteristics. 2. Epstein M, et al. Am J Manag Care 2015;21:S212–S220.

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting <https://contactazmedical.astrazeneca.com> or by calling 0800 783 0033.



DOSING & ADMINISTRATION CARD

LOKELMA is indicated for the treatment of hyperkalaemia in adult patients.<sup>1</sup>

RAASi DOWNTITRATION CAN CAUSE PROBLEMS DOWN THE LINE

RAASi downtitration is linked to over two times greater mortality risk vs optimal RAASi therapy.<sup>2</sup>  
**Prescribe LOKELMA to control hyperkalaemia while maintaining patients on optimal RAASi therapy.<sup>1</sup>**

Worsening of pre-existing heart failure during treatment was reported as a very common adverse reaction where most cases were resolved with appropriate clinical management without withdrawing Lokelma. The commonly reported adverse reactions were hypokalaemia, oedema related events and constipation.

Prescribing information and adverse event reporting information can be found on the last page of this card.

Promotional content intended for UK HCPs only.

\*Please consult the Summary of Product Characteristics for a full list of adverse reactions before prescribing.

## DOSING FOR ADULT (NON-DIALYSIS) PATIENTS

- Recommended dosing of LOKELMA to achieve and sustain normokalaemia<sup>1</sup>:

### CORRECTION PHASE

**1x**  **3 times**  
**10 g** **/day\*\***  
**for 24 to 48 hours**  
until normokalaemia is achieved\*\*

### MAINTENANCE PHASE

**1x**  **/day†**  
**5 g**

- To establish minimum effective dose, LOKELMA may be titrated
  - Up to **10 g once daily** or
  - Down to **5 g once every other day**
- No more than **10 g once daily** should be used for maintenance therapy

\*If normokalaemia is not achieved after 48 hours of treatment, the same regimen can be continued for an additional 24 hours. If normokalaemia is not achieved after 72 hours of treatment, other treatment approaches should be considered.<sup>1</sup>

†Patients who miss a dose should be instructed to take the next usual dose at their normal time.<sup>1</sup>



**45 mL  
of water**

- Mix LOKELMA with 45 mL of water for oral administration<sup>1</sup>
- Tasteless
- No special conditions for storage
- May be taken with or without food

Ensure patients stir well and drink suspension straight away while still cloudy (powder will not dissolve). Remind patients, if powder settles, to stir again before finishing the drink.<sup>1</sup>

## ORAL ADMINISTRATION

**LOKELMA should be administered at least 2 hours before or 2 hours after oral medications with clinically meaningful gastric pH-dependent bioavailability. Examples of medications include<sup>1</sup>:**

- **azole antifungals** (ketoconazole, itraconazole and posaconazole)
- **anti-HIV drugs** (atazanavir, nelfinavir, indinavir, ritonavir, saquinavir, raltegravir, ledipasvir and rilpivirine)
- **tyrosine kinase inhibitors** (erlotinib, dasatinib and nilotinib)
- **immunosuppressants** (tacrolimus)

LOKELMA can be taken without spacing of dosing times with oral medications that do not exhibit pH-dependent bioavailability.

### Consideration and monitoring requirements:<sup>1</sup>

Serum potassium should be monitored when clinically indicated, including after changes are made to medicinal products that affect the serum potassium concentration (e.g. RAASi or diuretics) and after the LOKELMA dose is titrated. Monitoring frequency will depend upon a variety of factors including other medicinal products, progression of chronic kidney disease and dietary potassium intake.

### Check special warnings and precautions for use:

**Hypokalaemia:**<sup>1</sup> In patients with severe hypokalaemia, LOKELMA should be discontinued and the patient re-evaluated.

**Intestinal perforation:**<sup>1</sup> Intestinal perforation has been reported with potassium binders, including LOKELMA. Therefore, specific attention should be paid to signs and symptoms related to intestinal perforation.

**Sodium content:**<sup>1</sup> LOKELMA is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

**Information presented here is not meant to replace the SmPC nor is it an exhaustive list of all information presented there. Please refer to the SmPC for full list of special warnings and precautions.**

**Worsening of pre-existing heart failure:** Patients with pre-existing heart failure, particularly those in whom an increased sodium intake may lead to fluid overload and decompensation, should be monitored for manifestations of worsening heart failure. These may include increased dyspnoea, oedema and rapid weight gain, and should be managed as per standard clinical practice. In a pooled analysis of three placebo-controlled clinical studies of LOKELMA in non-dialysis patients, most cases were resolved with appropriate clinical management without withdrawing LOKELMA.

## DOSING FOR PATIENTS ON CHRONIC HAEMODIALYSIS

- No changes from the normal doses are required for patients with renal impairment who are not on chronic haemodialysis
- For patients on dialysis LOKELMA should only be dosed on non-dialysis days
- Recommended dosing of LOKELMA to achieve and sustain normokalaemia<sup>1</sup>:

### RECOMMENDED STARTING DOSE FOR PATIENTS ON CHRONIC HAEMODIALYSIS

**1x**  **/non-dialysis days**  
**5 g**

- To establish normokalaemia (4.0 - 5.0 mmol/L), the dose may be titrated up or down weekly based on the pre-dialysis serum K<sup>+</sup> after the long interdialytic interval
- The dose could be adjusted at intervals of one week in increments of 5 g:

**- Up to 15 g once daily on non-dialysis days**

It is recommended to monitor serum K<sup>+</sup> weekly while the dose is adjusted. Once normokalaemia is established, potassium should be monitored regularly (e.g. monthly, or more frequently based on clinical judgement including changes in dietary potassium or medication affecting serum potassium).