

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. **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. **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: Lokelma has GB licences. 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.

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Adverse events should be reported. Reporting forms and information can be found at 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.