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 for adults and elderly is 10g, administered orally, three times a day as a suspension in water, with or without food. Empty entire contents of sachet into approximately 45ml of water, stir if powder settles. 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. Monitoring frequency will depend on factors such as other medications, progression of chronic kidney disease and dietary potassium intake. Discontinue and re-evaluate patient if severe hypokalaemia occurs. No clinical data available for treatment beyond one year.

**Renal/hepatic impairment:** No dosage adjustment required. **Paediatric population:** Safety and efficacy has not been established in children and adolescents (<18 years).

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

**Warnings and precautions:** 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. 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. During correction phase, a lengthening of QT interval can be observed as the physiologic result of decline in serum potassium concentration. Sodium zirconium cyclosilicate may be opaque to X-rays, keep in mind if patient has abdominal X-ray. Risk of intestinal perforation unknown. Special attention to be paid as intestinal perforation has been reported with polymers that act in the gastrointestinal tract. No experience with patients receiving dialysis treatment. Limited experience in patients with serum potassium concentrations greater than 6.5 mmol/L. Preferable to avoid use during pregnancy. Can be used during breast-feeding.

**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 medications with clinically meaningful gastric pH dependent bioavailability (e.g. azole antifungals, a number of anti-HIV drugs, and tyrosine kinase inhibitors). Sodium zirconium cyclosilicate can be co-
administered without spacing of dosing times with oral medications that do not exhibit pH-dependent bioavailability.

Undesirable events: Consult SmPC for full list of side effects. Common: Hypokalaemia, oedema related events (including fluid overload, fluid retention, generalised oedema, hypervolaemia, localised oedema, oedema, oedema peripheral, peripheral swelling).

Legal category: POM.

Marketing authorisation numbers: EU/1/17/1173/002-004

Presentation and Basic NHS cost: 5g x 30 pack: £213.60; 10g x 3 pack: £42.72; 10g x 30 pack: £427.20.


Further information is available from: AstraZeneca UK Ltd., 600 Capability Green, Luton, LU1 3LU, UK.

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

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to AstraZeneca by visiting https://aereporting.astrazeneca.com/ or by calling 0800 783 0033.