



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 January 2018  
EMA/CHMP/24825/2018 Rev. 2  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Lokelma

#### sodium zirconium cyclosilicate

On 25 January 2018 the Committee for Medicinal Products for Human Use (CHMP) confirmed its previous positive opinion and recommended the granting of a marketing authorisation for the medicinal product Lokelma. This follows an inspection of the manufacturing site for Lokelma's active substance confirming that the site is compliant with good manufacturing practice.

Lokelma is intended for the treatment of hyperkalaemia. The applicant for this medicinal product is AstraZeneca AB.

Lokelma will be available as 5-g and 10-g powder for oral suspension. The active substance of Lokelma is sodium zirconium cyclosilicate (ATC code: V03AE10). Sodium zirconium cyclosilicate selectively binds potassium in exchange for hydrogen and sodium cations throughout the gastrointestinal (GI) tract and reduces the concentration of free potassium in the GI lumen. This lowers serum potassium levels by drawing potassium into the GI tract and increasing faecal potassium excretion to resolve hyperkalaemia.

The benefits with Lokelma are its ability to lower serum potassium levels. The most common side effects are hypokalaemia and oedema related events.

The full indication is: "treatment of hyperkalaemia in adult patients".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

