Brand Name: Lokelma
Generic: sodium zirconium cyclosilicate
Type:
Year Accepted/Phase: 2018

Mechanism:

Sodium zirconium cyclosilicate is a non-absorbed zirconium silicate that preferentially captures potassium ions in exchange for sodium ions in the gastrointestinal tract, reducing serum potassium levels.

Chemical Structure: N/A

Indication:

Lokelma is indicated for the treatment of hyperkalemia in adults, providing both rapid reduction of high potassium levels and maintenance of normokalemia with long-term use.

Clinical trials:

ZS-003 Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/25415807/
Purpose: Assess the efficacy and safety of sodium zirconium cyclosilicate in patients with hyperkalemia.
Dates: Conducted from 2011 to 2013.
Results: The ZS-003 trial demonstrated that sodium zirconium cyclosilicate significantly reduced serum potassium levels within 48 hours of treatment initiation compared to placebo. The study showed a dose-dependent reduction in potassium levels and a good safety profile.
Impact: These results provided strong evidence for the rapid and effective reduction of serum potassium levels in patients with hyperkalemia.

ZS-004 and ZS-004E Trials (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/25415807/
Purpose: Evaluate the long-term efficacy and safety of sodium zirconium cyclosilicate in maintaining normokalemia (normal potassium levels) after initial treatment.
Dates: Conducted from 2011 to 2014.
Results: The ZS-004 trial demonstrated that sodium zirconium cyclosilicate effectively maintained normal potassium levels over a 28-day treatment period compared to placebo. The ZS-004E trial, an extension study, showed that long-term treatment with sodium zirconium cyclosilicate was well-tolerated and continued to maintain normokalemia for up to one year.
Impact: These results supported the use of sodium zirconium cyclosilicate for both acute and long-term management of hyperkalemia.

HARMONIZE Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/25402495/
Purpose: Confirm the efficacy and safety of sodium zirconium cyclosilicate in patients with hyperkalemia.
Dates: Conducted from 2012 to 2014.
Results: The HARMONIZE trial confirmed that sodium zirconium cyclosilicate rapidly reduced serum potassium levels and maintained normal levels over 28 days of treatment. The trial also showed a favorable safety profile with few adverse events.
Impact: These results provided additional evidence of the efficacy and safety of sodium zirconium cyclosilicate in the treatment of hyperkalemia.