Generic Name:
Sodium zirconium cyclosilicate
Trade Name:
Lokelma
Company:
AstraZeneca
Notes:

AstraZeneca announced FDA approval of sodium zirconium cyclosilicate, a highly selective, oral potassium?removing agent, to treat adults with hyperkalaemia. The agent is formulated as a powder for oral suspension and administered orally.

Hyperkalaemia occurs in 23% to 47% of patients with chronic kidney disease and/or heart failure, with an estimated 200 million and 38 million people, respectively, living with each condition worldwide. The condition may lead to cardiac arrest and death, with mortality being up to 30% in patients with severe hyperkalaemia, if not treated rapidly.

The risk of hyperkalaemia increases significantly for patients with chronic kidney disease and for those who take common medications for heart failure, such as renin-angiotensin-aldosterone system (RAAS) inhibitors, which can increase potassium in the blood. To help prevent the recurrence of hyperkalaemia, RAAS-inhibitor therapy is often modified or discontinued, which can compromise cardio-renal outcomes and increase the risk of death.

FDA approval was supported by data from three double-blind, placebo-controlled trials and two open-label trials. For patients receiving sodium zirconium cyclosilicate, the onset of action was at 1 hour, and the median time to achieving normal potassium levels in the blood was 2.2 hours, with 92% of patients achieving normal potassium levels within 48 hours from baseline. The treatment effect was maintained for up to 12 months.

Medication Monitor Categories:
New Drug Approvals