

Lokelma[™] (sodium zirconium cyclosilicate) – New drug approval

- On May 18, 2018, <u>AstraZeneca announced</u> the <u>FDA approval</u> of <u>Lokelma (sodium zirconium cyclosilicate)</u>, for the treatment of hyperkalemia in adults.
 - Lokelma should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.
- Hyperkalemia is a serious condition in which serum potassium levels are elevated. Patients with an
 increased risk of hyperkalemia include those with chronic kidney disease, heart failure, diabetes,
 and those taking renin-angiotensin-aldosterone system inhibitors.
- Lokelma is an insoluble, non-absorbed sodium zirconium silicate that acts as a highly-selective potassium-removing agent.
- The safety and efficacy of Lokelma were based on data from two double-blind, placebo-controlled studies and two open-label studies in adult patients with hyperkalemia.
 - The placebo-controlled studies demonstrated that patients treated with Lokelma had significant reductions in serum potassium levels vs. placebo-treated patients.
 - The two open-label studies showed that the treatment effect of Lokelma on serum potassium was maintained during continued therapy.
- Warnings and precautions of Lokelma include gastrointestinal adverse events in patients with motility disorders and edema.
- The most common adverse reactions with Lokelma were mild to moderate edema.
- The recommended starting dose of Lokelma is 10 g administered orally three times a day for up to 48 hours. For maintenance treatment, the recommended dose is 10 g once daily.
 - Lokelma is administered as a suspension in water.
 - During maintenance treatment, the dose may be adjusted at one-week intervals as needed (by 5 g daily) to obtain desired potassium target range.
 - Serum potassium should be monitored and the dose adjusted based on the serum potassium level and desired target range.
- AstraZeneca's plans to launch Lokelma are pending. Lokelma will be available as 5 g and 10 g packets for oral suspension.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.