Recommended Dosing for LOKELMA

For patients who are NOT on dialysis

INITIAL TREATMENT

TAKE ONE
10-g PACKET
3X/DAY
FOR UP TO 48 HOURS (2 DAYS)

MAINTENANCE TREATMENT

TAKE ONE
10-g PACKET
1X/DAY

- Monitor serum potassium and adjust the dose of LOKELMA based on the serum potassium level and desired target range
- During maintenance treatment, up-titrate based on the serum potassium level at intervals of 1 week or longer and in increments of 5 g
- The recommended maintenance dose range is from 5 g qod to 15 g daily
- Decrease the dose of LOKELMA or discontinue if the serum potassium is below the desired target range

qod=every other day.

For patients who ARE on chronic hemodialysis

RECOMMENDED DOSE

TAKE ONE
5-g PACKET
1X/DAY
ON NON-DIALYSIS DAYS

- The recommended starting dose is 5 g once daily on non-dialysis days
- Consider a starting dose of 10 g once daily on non-dialysis days in patients with serum potassium >6.5 mEq/L

- Monitor serum K^+ and adjust the dose of LOKELMA based on the pre-dialysis serum K^+ value after the LIDI and desired target range
- During initiation and after a dose adjustment, assess serum potassium after 1 week
- Recommended maintenance dose range is from 5 g to 15 g once daily, on non-dialysis days
- Discontinue or decrease the dose of LOKELMA if:
  - Serum K^+ falls below the desired target range based on the pre-dialysis value after the LIDI, or
  - The patient develops clinically significant hypokalemia

LIDI=long interdialytic interval.

IMPORTANT SAFETY INFORMATION FOR LOKELMA® (sodium zirconium cyclosilicate)

WARNINGS AND PRECAUTIONS:

- **Gastrointestinal Adverse Events in Patients with Motility Disorders:** Avoid LOKELMA in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders. LOKELMA has not been studied in patients with these conditions and it may be ineffective and may worsen gastrointestinal conditions.

Please see additional Important Safety Information on next page and full Prescribing Information.

LOKELMA®
(sodium zirconium cyclosilicate)
5 g | 10 g for oral suspension

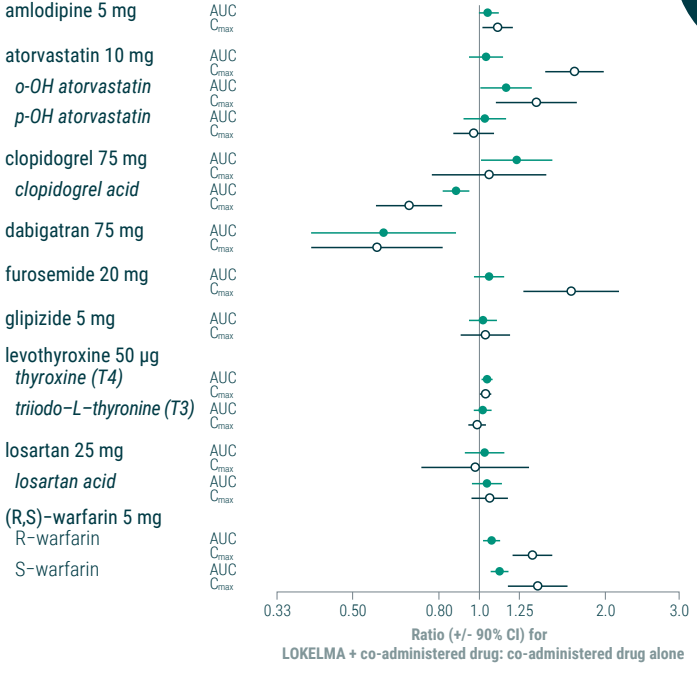
LOKELMA may affect the exposure of other orally administered medications

36 drugs were tested to determine potential interactions with LOKELMA

- **16 drugs tested showed no in vitro interaction with LOKELMA: allopurinol, apixaban, aspirin, captopril, cyclosporine, digoxin, ethinyl estradiol, lisinopril, magnesium, metformin, phenytoin, prednisone, propranolol, quinapril, spironolactone, and ticagrelor**
- 9 of the 20 drugs that showed an in vitro interaction were subsequently tested in vivo in healthy volunteers
  - Losartan, glipizide, and levothyroxine did not show any changes in exposure when co-administered with LOKELMA
  - There was an increase in systemic exposure to weak acids such as furosemide and atorvastatin when co-administered with LOKELMA
  - There was a decrease in systemic exposure to weak bases such as dabigatran when co-administered with LOKELMA
- LOKELMA can transiently increase gastric pH. As a result, LOKELMA can change the absorption of co-administered drugs that exhibit pH-dependent solubility, potentially leading to altered efficacy or safety of these drugs when taken close to the time LOKELMA is administered
- In general, other oral medications should be administered at least 2 hours before or 2 hours after LOKELMA
- LOKELMA is not expected to impact systemic exposure of drugs that do not exhibit pH-dependent solubility and so spacing is not needed if it has been determined that the concomitant medication does not exhibit pH-dependent solubility

DRUG INTERACTIONS

Effects of LOKELMA on the Pharmacokinetic Exposures of Other Orally Administered Medications



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Reconstitution and administration

- In general, other oral medications should be administered at least 2 hours before or after LOKELMA
- Empty the entire contents of the packet(s) into a drinking glass containing approximately 3 tablespoons of water or more, if desired
- Stir well and drink immediately
- If powder remains in the glass, add water, stir, and drink immediately. Repeat until no powder remains to ensure the entire dose is taken
- LOKELMA can be taken with or without food

LOKELMA is tasteless and odorless

- LOKELMA comes in 5-g or 10-g white powder in a foil-lined packet for oral suspension
- Store between 59°F and 86°F; no refrigeration required

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D):

- **Edema:** Each 5-g dose of LOKELMA contains approximately 400 mg of sodium, but the extent of absorption by the patient is unknown. In clinical trials of LOKELMA in patients who were not on dialysis, edema was observed and was generally mild to moderate in severity and was more commonly seen in patients treated with 15 g once daily. Monitor for signs of edema, particularly in patients who should restrict their sodium intake or are prone to fluid overload (eg, heart failure or renal disease). Advise patients to adjust dietary sodium, if appropriate. Increase the dose of diuretics as needed.

  In a clinical trial of LOKELMA in patients on chronic hemodialysis in which most patients were treated with doses of 5 g to 10 g once daily on non-dialysis days, there was no difference in the mean change from baseline in interdialytic weight gain (a measure of fluid retention) between the LOKELMA and placebo groups.
- **Hypokalemia in Patients on Hemodialysis:** Patients on hemodialysis may be prone to acute illness that can increase the risk of hypokalemia on LOKELMA (eg, illnesses associated with decreased oral intake, diarrhea). Consider adjusting LOKELMA dose based on potassium levels in these settings.

ADVERSE REACTIONS: The most common adverse reaction in non-dialysis patients with LOKELMA was mild to moderate edema. In placebo-controlled trials up to 28 days, edema was reported in 4.4%, 5.9%, 16.1% of non-dialysis patients treated with 5 g, 10 g, and 15 g of LOKELMA once daily, respectively vs 2.4% of non-dialysis patients receiving placebo.

DRUG INTERACTIONS: LOKELMA can transiently increase gastric pH. In general, oral medications with pH-dependent solubility should be administered at least 2 hours before or 2 hours after LOKELMA. Spacing is not needed if it has been determined the concomitant medication does not exhibit pH-dependent solubility.

INDICATION AND LIMITATION OF USE

LOKELMA is indicated 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.

Please see full Prescribing Information

You may report side effects related to AstraZeneca products by clicking here.

Reference: LOKELMA® (sodium zirconium cyclosilicate) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2020.

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