## WHEN TREATING HYPERKALEMIA CHOOSE THE PATH TO SUSTAINED\* K+ CONTROL¹ LOKELMA is the only FDA-approved K<sup>+</sup> binder with efficacy and safety results in the label for adult patients with hyperkalemia on chronic hemodialysis¹ \*Based on pre-dialysis serum K+ levels in an 8-week trial in which patients received LOKELMA or placebo on non-dialysis days.1 INDICATION AND LIMITATION OF USE LOKELMA® 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. (sodium zirconium cyclosilicate) 5g | 10g for oral suspension Please read additional Important Safety Information and full Prescribing Information by clicking buttons below.

HYPERKALEMIA RECURRENCE AND RISK

PATIENT PROFILE

MOA

**EFFICACY** 

SAFETY

DOSING

ACCESS

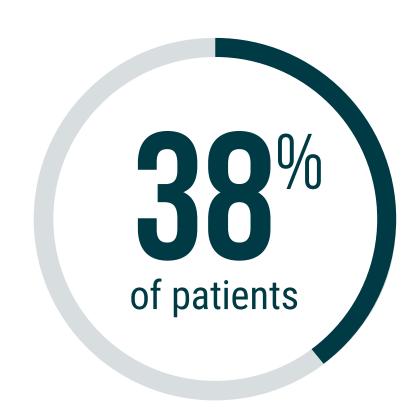
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**REFERENCES** 

SUMMARY

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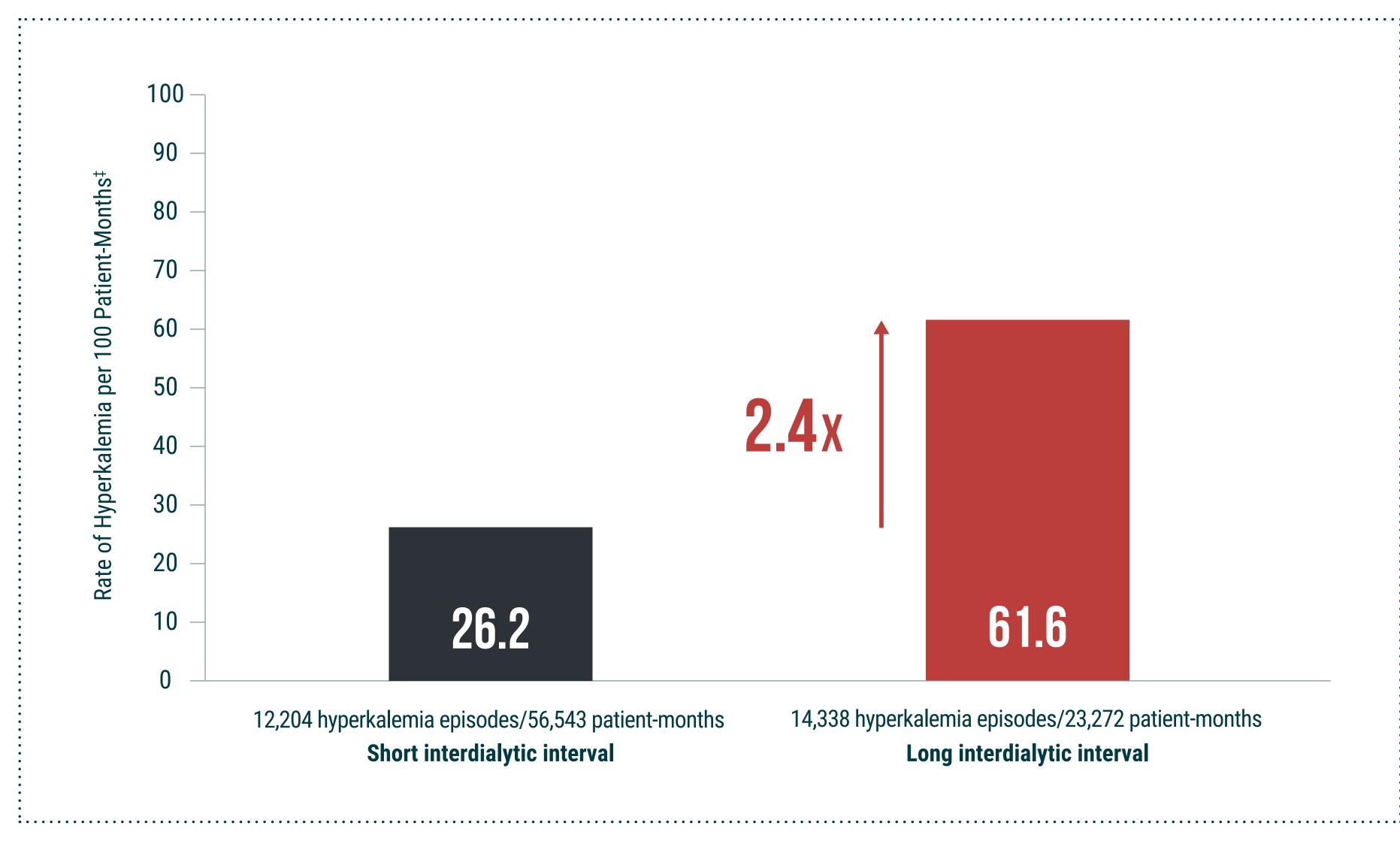
### HYPERKALEMIA IS PREVALENT IN PATIENTS ON HEMODIALYSIS<sup>2,3</sup>



**DESPITE RECEIVING IN-CENTER** HEMODIALYSIS, HYPERKALEMIA WAS FOUND IN 38% OF PATIENTS IN **US DIALYSIS CENTERS IN FEBRUARY** 2020 (N=7959)\*2

In a retrospective observational study, where hyperkalemia was defined as  $K^+ \ge 5.5$  mEq/L

Prevalence of hyperkalemia was found to be 2.4x higher in hemodialysis patients during the day after the long interdialytic interval vs the day after the short interdialytic interval<sup>†4</sup>



The short interdialytic interval was defined as a single day between sessions. The long interdialytic interval was defined as multiple days between sessions.

The short interdialytic interval was defined as a single day between sessions. The long interdialytic interval was defined as multiple days between sessions.

\*Data from the DOPPS Practice Monitor using the most recent (single) monthly pre-dialysis values of serum K+ levels from the national sample of >11,000 patients in >200 US hemodialysis centers. Note: Hyperkalemia is defined as K<sup>+</sup> ≥5.0 mEq/L. Timing of K<sup>+</sup> measurement in relation to the hemodialysis schedule, whether after a long or short interdialytic interval, is unknown.<sup>2</sup>

<sup>†</sup>A retrospective observational study from the USRDS of hemodialysis patients (N=36,888) during 2010 with ≥6 hemodialysis sessions and ≥1 K<sup>+</sup> measurement. Serum K<sup>+</sup> was typically measured once a month during routine sessions. The hemodialysis schedule was 3 times weekly.4

‡Rate of hyperkalemia was computed as a ratio of total number of hyperkalemia episodes and cumulative follow-up time in months. The LIDI rate was calculated based on hyperkalemia episodes identified on the day after the LIDI and the SIDI rate was calculated based on hyperkalemia episodes identified on the day after the SIDI.4

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DOSING

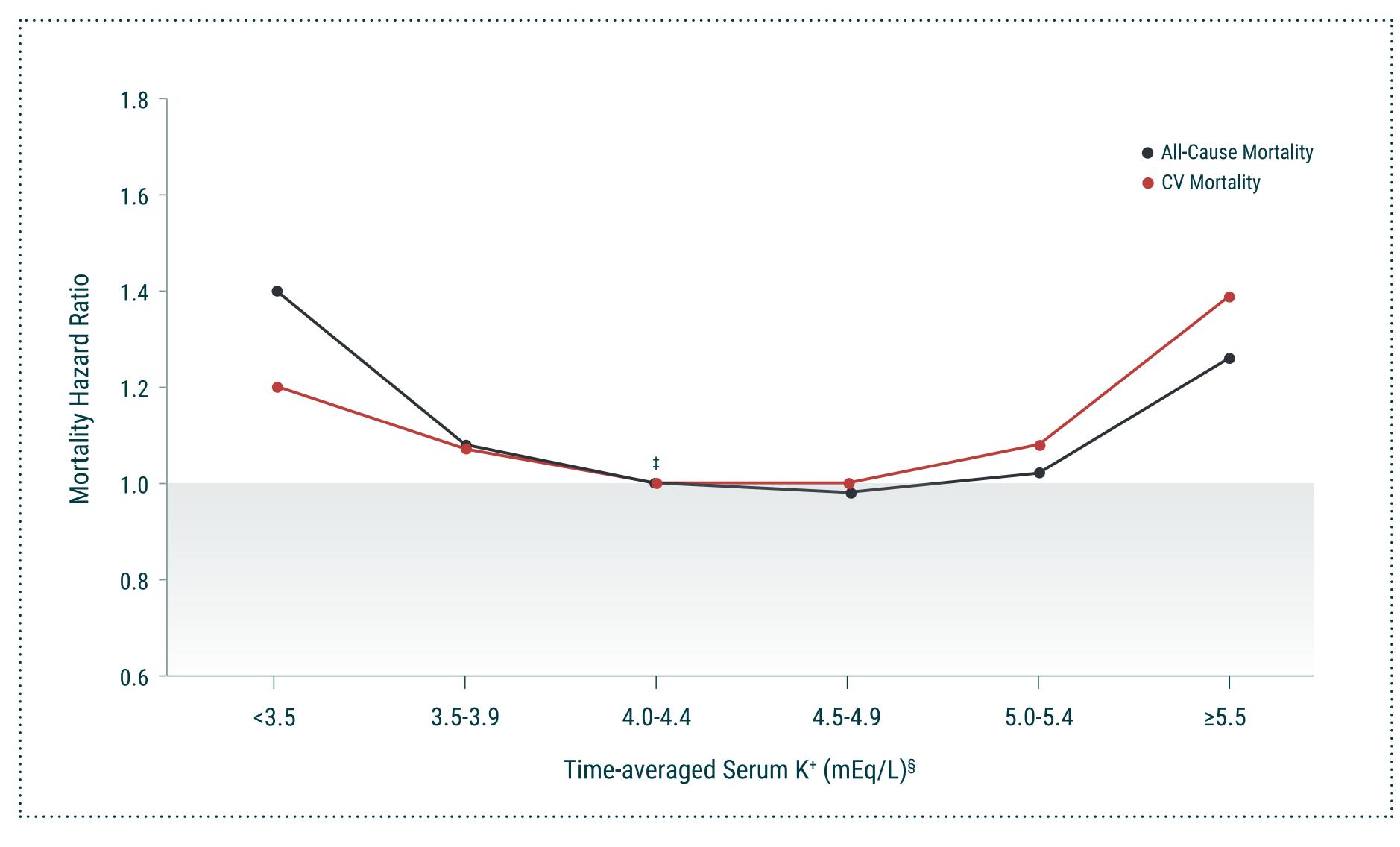
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### HYPERKALEMIA POSES RISKS OF HOSPITALIZATION AND MORTALITY<sup>2,3</sup>



IN A RETROSPECTIVE **OBSERVATIONAL STUDY OF ESRD PATIENTS RECEIVING THRICE-WEEKLY HEMODIALYSIS** (N=52,734), SERUM K<sup>+</sup> ≥5.5 mEq/L WAS ASSOCIATED WITH **INCREASED ADJUSTED RISK OF ALL-CAUSE HOSPITALIZATION\*5** 

#### Hyperkalemia is associated with an increased risk of all-cause and CV mortality in patients receiving hemodialysis<sup>†3</sup>



Graph reproduced from Torlén et al. 2012.

LOKELMA® (sodium zirconium cyclosilicate) is not indicated to reduce the risk of death or hospitalizations.<sup>1</sup>

\*Based on an analysis of 533,889 qualifying serum K<sup>+</sup> measurements from US Medicare adult patients at a large dialysis organization with at least 1 K<sup>+</sup> measurement between January 2010 and December 2011. Serum K<sup>+</sup> measurements were generally performed monthly immediately prior to HD on the first or second treatment day after the long weekend (ie, Monday or Wednesday for a Monday-Wednesday-Friday schedule). Analyses were adjusted for covariates including demographics, comorbidities, and laboratory values.5

†Analysis of 111,434 hemodialysis patients with follow-up data from an observational cohort study conducted in US DaVita facilities between July 2001 and June 2006. Hyperkalemia defined as K<sup>+</sup> ≥5.0 mEq/L. The timing of K<sup>+</sup> measurement in relation to the hemodialysis cycle and schedule was not described in the study. Data were adjusted for demographics, comorbidities, and laboratory values.3 <sup>‡</sup>Reference group was hemodialysis patients with serum K<sup>+</sup> between 4.0 mEq/L and 4.5 mEq/L.<sup>3</sup>

§Each patient had K<sup>+</sup> measurements performed at least monthly. The average of all repeated measures was done quarterly for 20 calendar quarters to calculate the time-averaged serum K<sup>+</sup>.3

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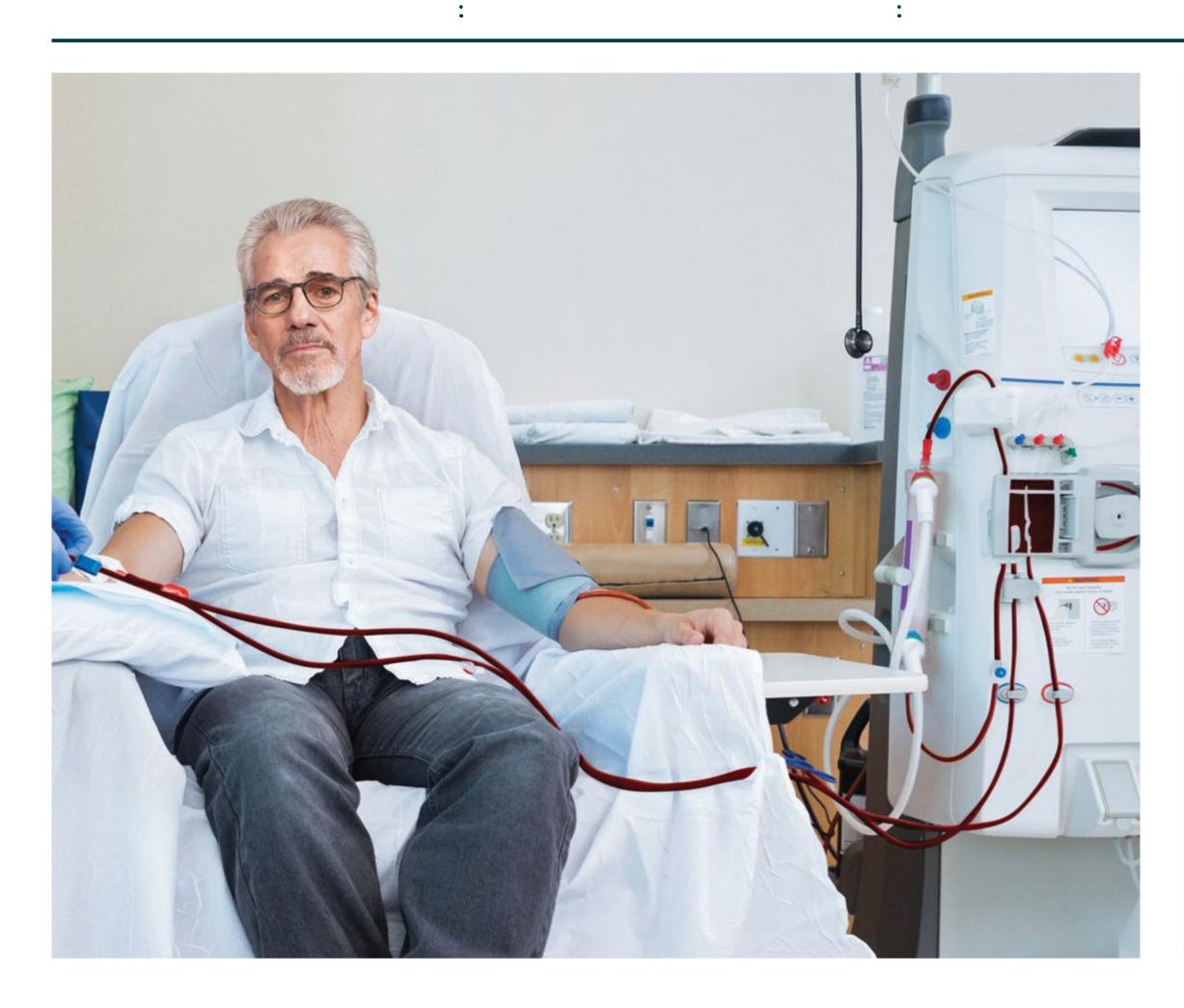


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### HAVE YOU CONSIDERED K\* BINDERS FOR YOUR PATIENTS ON CHRONIC HEMODIALYSIS WITH HYPERKALEMIA?

Age 58

ESRD, diabetes, on chronic hemodialysis with persistent hyperkalemia



I spend so much time at the treatment center on dialysis being reminded of my condition. But even on my off days, when I'm home, I have to worry about my high potassium. Every day feels like a challenge.



#### **PRESENTATION**

► Tim has been previously hospitalized for hyperkalemia

Pre-dialysis serum K <sup>+</sup> after the LIDI	6.2 mEq/L		
Blood pressure	130/90 mmHg		
Kt/V	1.4		
Dialysate K <sup>+</sup> concentration	2.0 mEq/L		

#### MANAGEMENT OPTIONS FOR TREATING HYPERKALEMIA IN PATIENTS ON CHRONIC HEMODIALYSIS:

- Prescribing K<sup>+</sup> binders
- Prescribing a low-K<sup>+</sup> diet

- Adjusting dialysis prescription
- Modifying other medications

PRESCRIBED LOKELMA ON NON-DIALYSIS DAYS: Achieved and sustained normal pre-dialysis serum K<sup>+</sup> levels with continued use

Individual is a hypothetical patient, not an actual patient.

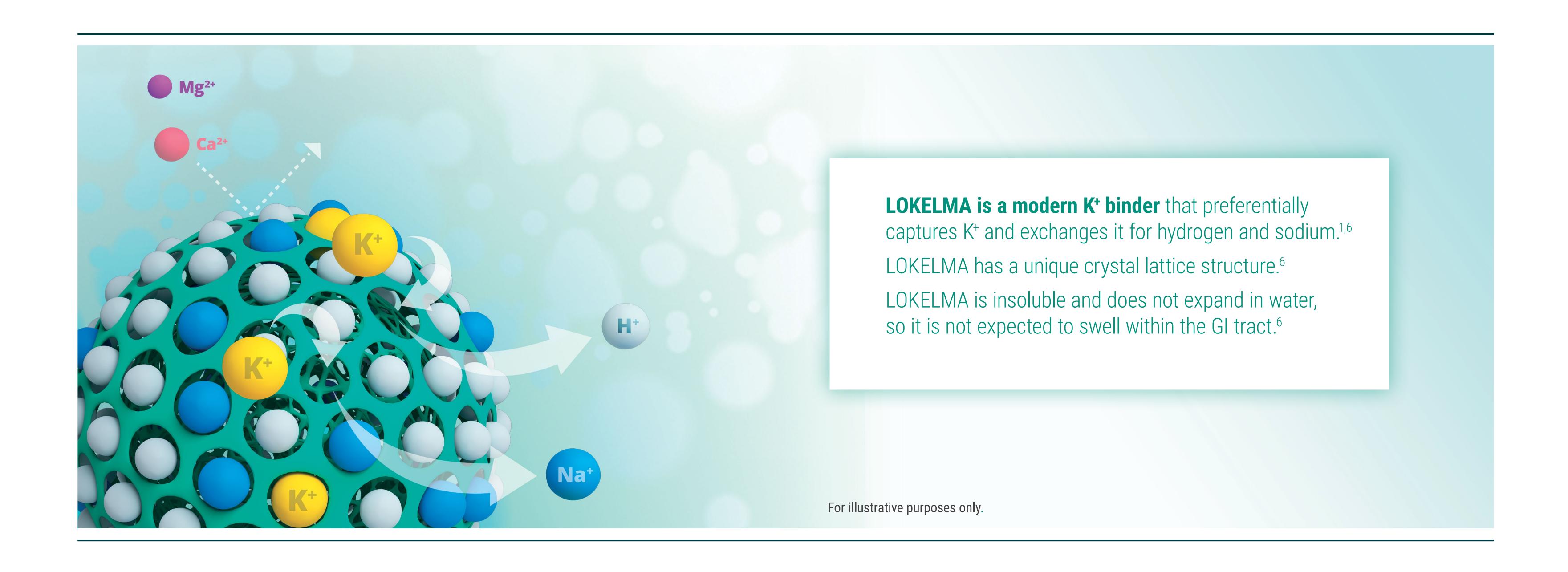
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### LOKELMA IS A HIGHLY SELECTIVE, INNOVATIVE K+ BINDER¹



### IMPORTANT SAFETY INFORMATION FOR LOKELMA 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.
- ► **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.

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## LOKELMA IS DIFFERENT THAN OTHER K+ BINDERS<sup>1,6</sup>

	LOKELMA	SPS (sodium polystyrene sulfonate)*7	<b>Veltassa</b> ® (patiromer) for oral suspension <sup>8</sup>
Selectivity	Binds K <sup>+†1</sup>	Binds K <sup>+</sup> , Ca <sup>+</sup> , and Mg <sup>+7</sup>	Binds K <sup>+</sup> and Mg <sup>+8</sup>
Site of K <sup>+</sup> capture in lumen of GI tract	Small and large intestines <sup>‡6</sup>	Primarily large intestine9	Primarily colon§9
Calcium content	$0 g^{10}$	$0 g^{10}$	1.6 g per 8.4 g of patiromer <sup>11</sup>
Sodium content for recommended maintenance dose range	400 mg qod- 1200 mg daily <sup>  1</sup>	1500 mg- 6000 mg daily <sup>¶12,13</sup>	012,13
Molecular composition	Non-polymer <sup>14</sup>	Polymer <sup>14</sup>	Polymer <sup>14</sup>
Volume of water for administration	~44 mL per dose <sup>#1</sup>	Powder: 45-60 mL per dose#7 Suspension: 60 mL per dose#15	~79 mL per dose#8

<sup>\*</sup>Brand names for SPS include Kayexalate® and Kionex®.

Clinical pharmacology does not correlate with efficacy or safety.

Veltassa is a registered trademark of Relypsa, Inc., a Vifor Pharma Group Company. Kayexalate was a registered trademark of Concordia Pharmaceuticals, Inc. Kionex is a registered trademark of Paddock Laboratories, LLC.

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<sup>†</sup>In vitro, LOKELMA has a high affinity for K<sup>+</sup>, even in the presence of other cations such as calcium and magnesium.<sup>1</sup>

<sup>&</sup>lt;sup>‡</sup>In vitro study; based on simulated intestinal fluid.<sup>6</sup>

<sup>§</sup>Based on nonclinical and early-phase studies.¹6

<sup>&</sup>quot;The sodium content/unit dose of LOKELMA is 400 mg/5 g, but the extent of absorption by the patient is unknown. The recommended maintenance dose range for patients not on dialysis is 5 g to 15 g once daily, on non-dialysis days (sodium content: 400 mg-1200 mg daily on non-dialysis days).1

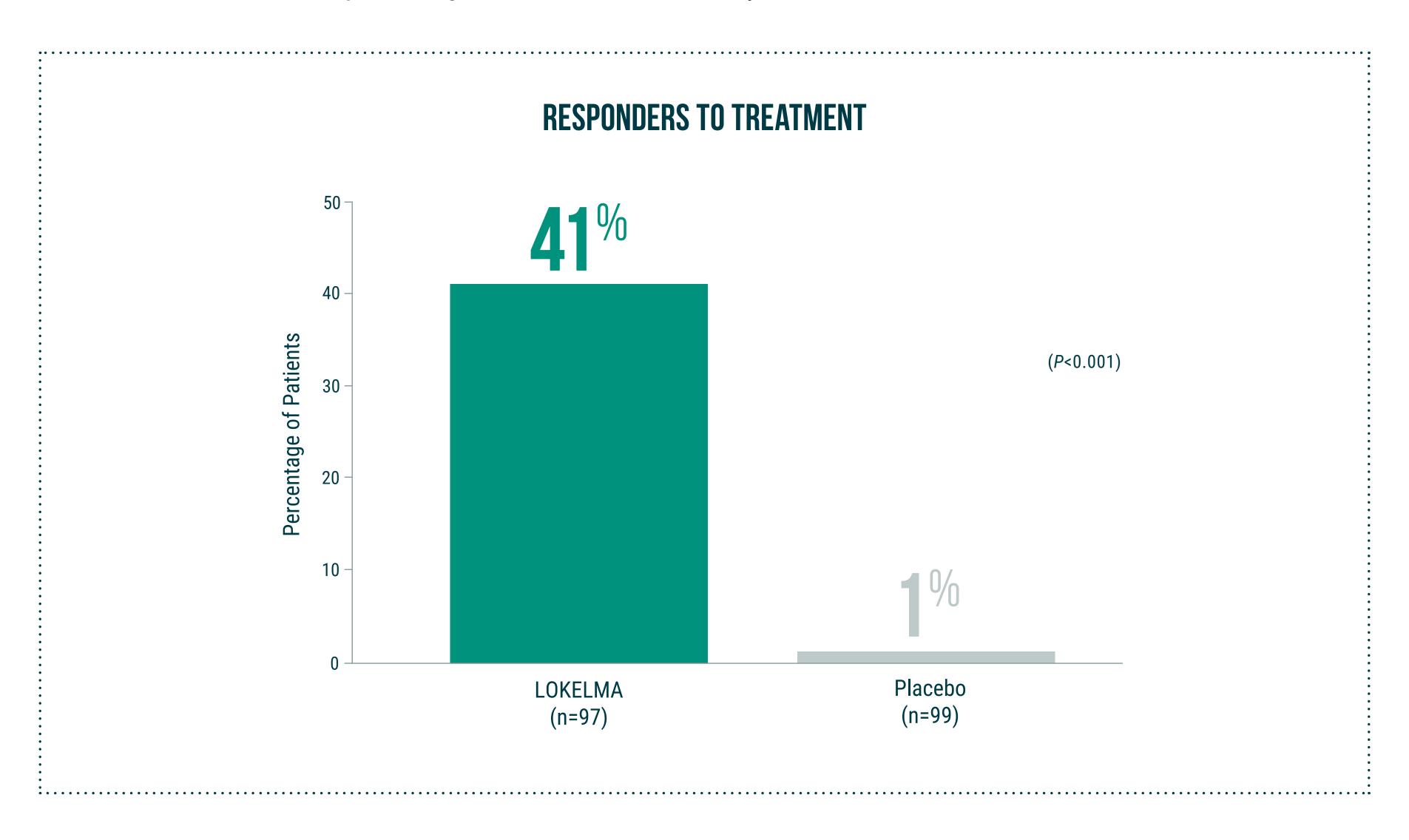
The sodium content/unit dose of SPS is 1500 mg/15 g. The in vivo efficiency of sodium-potassium exchange for SPS is approximately 33%; hence, about one-third of the actual sodium content is delivered to the body. The recommended dose for SPS is 15 g 1 to 4 times daily. 7,12,13

<sup>\*</sup>Patient can add more water if desired.

### SIGNIFICANTLY MORE PATIENTS ON DIALYSIS WERE RESPONDERS WHEN TREATED WITH LOKELMA VS PLACEBO

#### STUDY 4:

- ▶ 41% of patients treated with LOKELMA (n=97) achieved the primary endpoint compared to 1% of patients in the placebo group (n=99; P<0.001)
- Responders maintained pre-dialysis serum K<sup>+</sup> between 4.0-5.0 mEq/L during at least 3 of 4 hemodialysis treatments after the LIDI and did not receive rescue therapy\* during the evaluation period



DOSING

**ACCESS** 

STUDY 4 DESIGN: DIALIZE was a double-blind, placebo-controlled trial in patients with end-stage renal disease on chronic hemodialysis (≥3 months) and persistent hyperkalemia<sup>†</sup> (n=196) who were randomized to receive LOKELMA 5 g or placebo once daily on non-dialysis days. In the initial 4-week period the dose could be adjusted weekly in 5-g increments up to 15 g qd on non-dialysis days to achieve pre-dialysis serum K<sup>†</sup> levels between 4.0 mEq/L and 5.0 mEq/L after the LIDI. The dose at the end of the dose-adjustment period was maintained throughout the 4-week evaluation period. Baseline mean pre-dialysis serum K<sup>†</sup> levels after the LIDI were 5.8 mEq/L in the LOKELMA group and 5.9 mEq/L in the placebo group.<sup>1</sup>

**SAFETY** 

#### IMPORTANT SAFETY INFORMATION FOR LOKELMA (cont'd)

**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.

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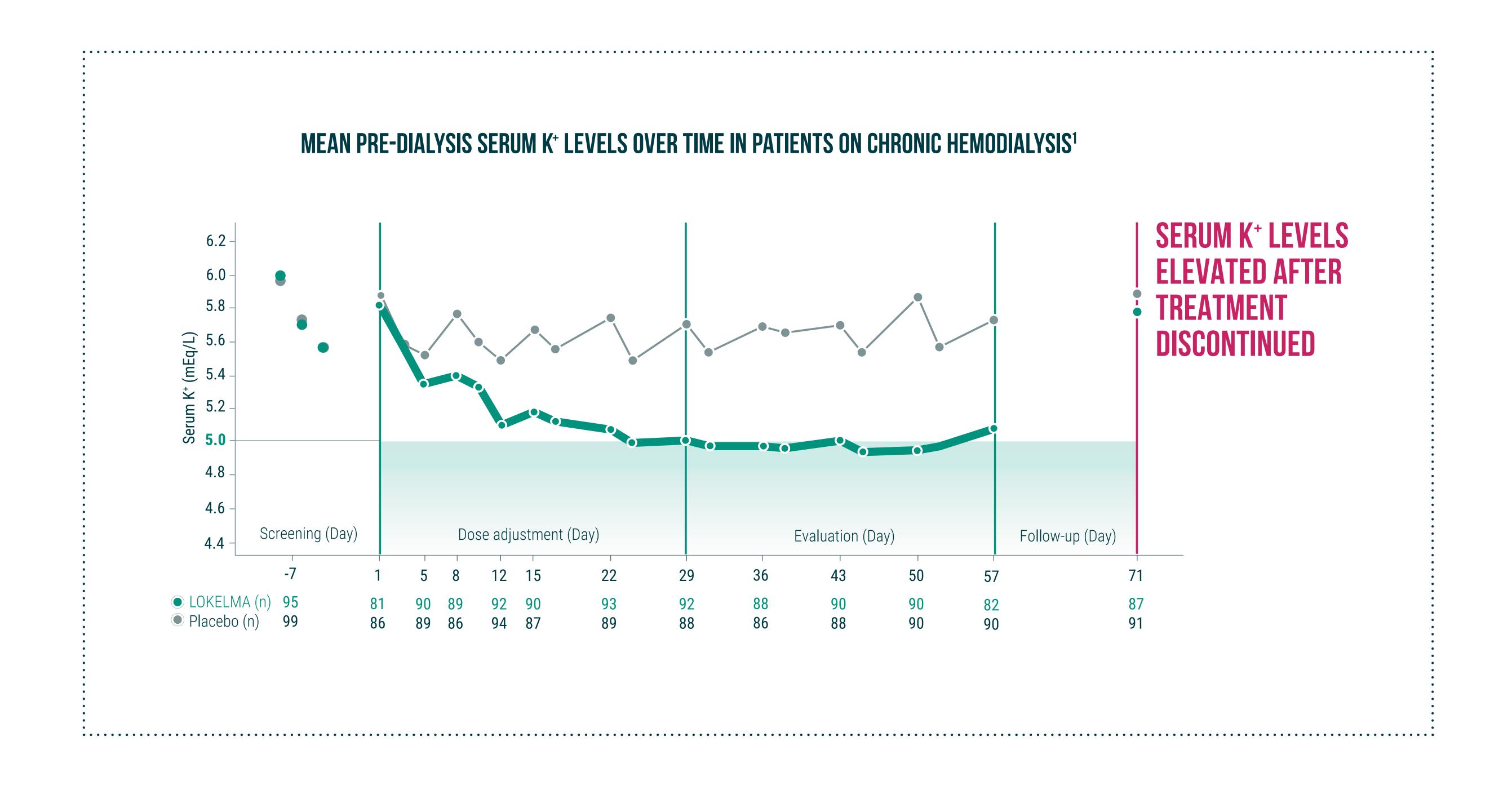
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<sup>\*</sup>Rescue therapy was defined as any urgent therapeutic intervention considered necessary to reduce serum K<sup>+</sup> in the setting of severe hyperkalemia (defined by protocol as >6.0 mEq/L). Rescue therapy use was left to the investigator's clinical judgment to be given in accordance with local practice guidelines.<sup>17</sup>

<sup>&</sup>lt;sup>†</sup>Persistent hyperkalemia defined as pre-dialysis serum K<sup>+</sup> >5.4 mEq/L after the LIDI and >5.0 mEq/L after at least one SIDI.<sup>1</sup>

## LOKELMA SUSTAINED LOWER PRE-DIALYSIS K<sup>+</sup> LEVELS IN PATIENTS ON HEMODIALYSIS WITH CONTINUED TREATMENT<sup>1</sup>



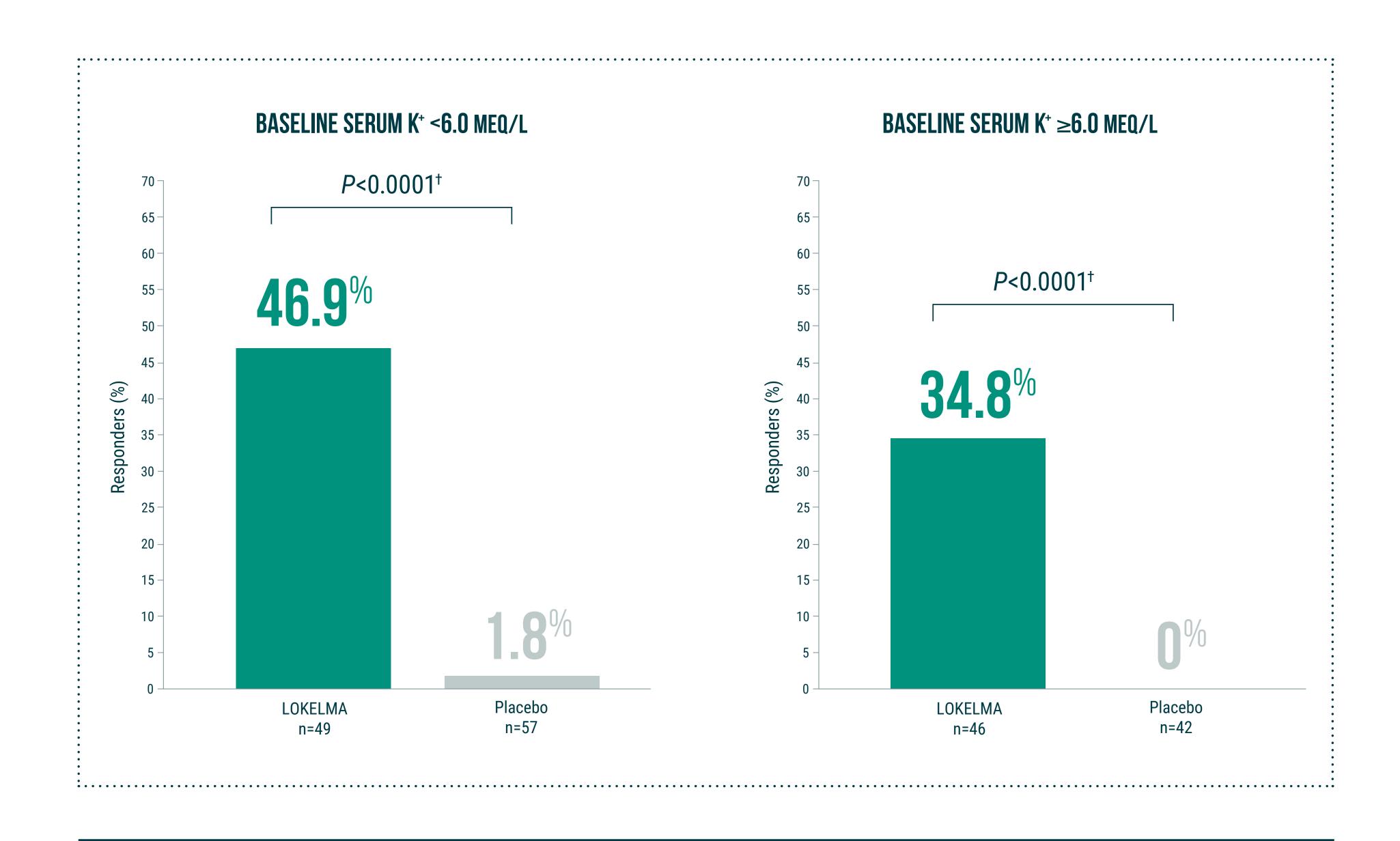


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DOSING

## MORE PATIENTS ON LOKELMA WERE RESPONDERS,\* REGARDLESS OF BASELINE SERUM K+ LEVEL<sup>17</sup>



Of patients who had at least one pre-dialysis serum K<sup>+</sup> value ≥6.0 mEq/L after a LIDI during the evaluation period (n=70), 80% were in the placebo group and 20% in the LOKELMA group<sup>17</sup>

\*Responders were defined as patients who, during the evaluation period, maintained a predialysis serum K⁺ 4.0-5.0 mEq/L during ≥3 out of 4 hemodialysis treatments following the long interdialytic interval and who did not receive rescue therapy.¹² values were obtained using a Fisher's exact test.

#### **IMPORTANT SAFETY INFORMATION FOR LOKELMA (cont'd)**

**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.

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**EFFICACY** 

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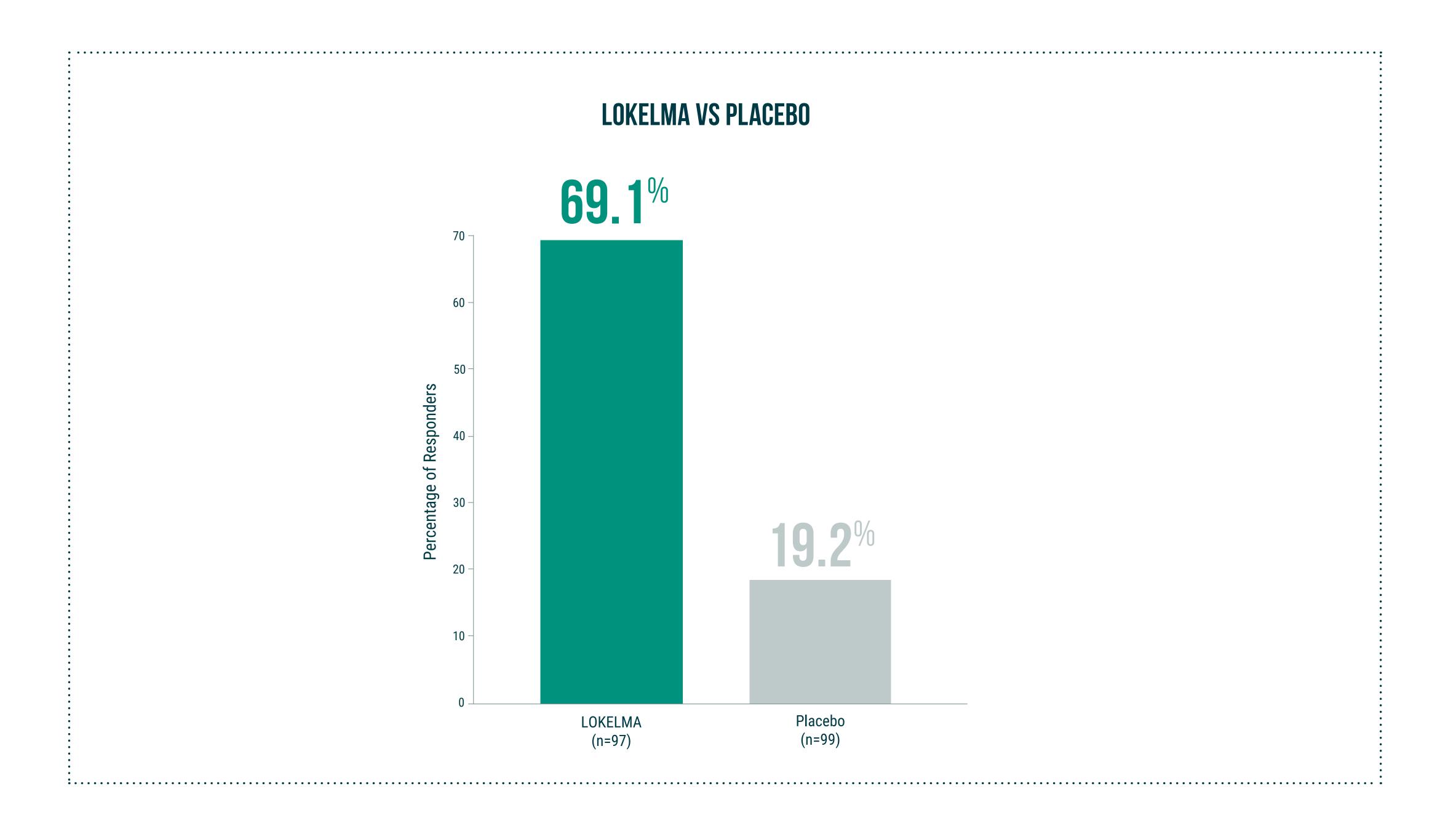
DOSING

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**REFERENCES** 

# MORE PATIENTS ON LOKELMA ACHIEVED AND MAINTAINED AN EXTENDED RANGE OF PRE-DIALYSIS SERUM K\* LEVELS<sup>18</sup>

MORE PATIENTS IN THE LOKELMA GROUP ACHIEVED AND MAINTAINED PRE-DIALYSIS SERUM K⁺ OF 4.0-5.5 mEq/L DURING ≥3 OUT OF 4 HEMODIALYSIS SESSIONS AFTER THE LIDI AND DID NOT REQUIRE RESCUE THERAPY IN THE EVALUATION PERIOD VS PLACEBO¹8



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### NO DIFFERENCE IN THE MEAN CHANGE FROM BASELINE IN IDWG BETWEEN THE LOKELMA AND PLACEBO GROUPS<sup>17</sup>

#### INTERDIALYTIC WEIGHT GAIN OVER TIME<sup>17</sup>

	LOKELMA (n=96)		<b>PLACEBO</b> (n=99)			
	n	Mean IDWG ± SD (kg)	Mean change from baseline ± SD (kg)*	n	Mean IDWG ± SD (kg)	Mean change from baseline ± SD (kg)*
Baseline <sup>†</sup>	96	3.0 ± 1.3		99	2.9 ± 1.6	
<b>Visit 11</b> (Day 29)	95	2.7 ± 3.7	-0.3 ± 3.6	97	2.8 ± 1.5	-0.1 ± 1.5
<b>Visit 15</b> (Day 57; EOT)	83	3.2 ± 1.3	0.2 ± 1.3	88	2.7 ± 1.6	-0.1 ± 1.6

- ► Most patients in Study 4 were treated with doses of 5 g to 10 g once daily on non-dialysis days<sup>17</sup>
- ► IDWG (a measure of fluid retention) was calculated as the difference between current pre-dialysis weight minus previous post-dialysis weight (measured at the immediate dialysis session prior to the visit)<sup>17</sup>

<sup>†</sup>Baseline IDWG was defined as the latest IDWG calculated over the LIDI during screening that occurred immediately prior to Visit 4 (Day 1).

### IMPORTANT SAFETY INFORMATION FOR LOKELMA 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.
- ▶ **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.

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DOSING

<sup>\*</sup>Based on programmatic calculations.

### THE SAFETY OF LOKELMA WAS COMPARABLE TO PLACEBO1

### OVERALL, 40 PATIENTS IN THE LOKELMA GROUP (41.7%) REPORTED ADVERSE EVENTS, COMPARED TO 46 PATIENTS IN THE PLACEBO GROUP (46.5%)<sup>1,17</sup>

	LOKELMA (n=97)	Placebo (n=99)
GI disorders	19.8%	17.2%
Infections	12.5%	9.1%
Overall SAEs	7.3%	8.1%

#### Hypokalemia

5% of patients developed pre-dialysis hypokalemia (serum K<sup>+</sup> <3.5 mEq/L) in both the LOKELMA and placebo groups; 3% and 1% of patients developed a serum K<sup>+</sup> <3.0 mEq/L in the LOKELMA</p> and placebo groups, respectively<sup>1</sup>

DOSING

ACCESS

#### **Other Adverse Events**

- ► The most common SAEs were angina pectoris (2.1%) in the LOKELMA group and hyperkalemia requiring rescue therapy (3%)\* and fluid overload (2%) in the placebo group<sup>17</sup>
- None of the SAEs were related to study drug<sup>17</sup>

\*Use of rescue therapy included but was not limited to insulin/glucose, sodium bicarbonate, β-adrenergic agonists, K+ binders (sodium polystyrene sulfonate, calcium polystyrene sulfonate, patiromer) and any other form of renal replacement therapy including additional dialysis or reduction in dialysate K<sup>+</sup> concentration.<sup>17</sup>

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### LOKELMA SHOULD ONLY BE DOSED ON NON-DIALYSIS DAYS<sup>1</sup>

#### **RECOMMENDED DOSE**



**5 g**1X/DAY
ON NON-DIALYSIS DAYS

- ► The recommended starting dose is 5 g once daily on non-dialysis days¹
- Consider a starting dose of 10 g once daily on non-dialysis days in patients with serum K<sup>+</sup> >6.5 mEq/L<sup>1</sup>
- ► Monitor serum K<sup>+</sup> and adjust the dose of LOKELMA based on the pre-dialysis serum K<sup>+</sup> value after the LIDI and desired target range<sup>1</sup>

DOSING

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- ► During initiation and after a dose adjustment, assess serum K<sup>+</sup> after 1 week<sup>1</sup>
- ► Recommended maintenance dose range is from 5 g to 15 g once daily, on non-dialysis days¹
- Discontinue or decrease the dose of LOKELMA if:
- -Serum K<sup>+</sup> falls below the desired target range based on the pre-dialysis value after the LIDI,<sup>1</sup> or
- -The patient develops clinically significant hypokalemia<sup>1</sup>

### IMPORTANT SAFETY INFORMATION FOR LOKELMA (cont'd) WARNINGS AND PRECAUTIONS (cont'd):

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.

Please read additional Important Safety Information and full Prescribing Information by clicking buttons below.



### LOKELMA IS TASTELESS AND ODORLESS<sup>1,19</sup>



#### **HOW TO DOSE LOKELMA**

- ► LOKELMA is a white to grey powder available as 5 g or 10 g foil-lined packet for oral suspension<sup>1</sup>
- ► Administer LOKELMA orally as a suspension in water¹
- Empty the entire contents of the packet(s) into a drinking glass containing approximately 3 tablespoons of water or more, if desired

DOSING

ACCESS

- Stir well and drink immediately<sup>1</sup>
- ► If powder remains in the glass, add water, stir, and drink immediately. Repeat until no powder remains¹

In general, other oral medications should be administered at least 2 hours before or 2 hours after taking LOKELMA.1

### **PATIENTS**

HYPERKALEMIA RECURRENCE AND RISK

PATIENT PROFILE

- Should be advised to adjust dietary sodium, if appropriate<sup>1</sup>
- Can take LOKELMA with or without food¹
- Do not need to refrigerate LOKELMA¹



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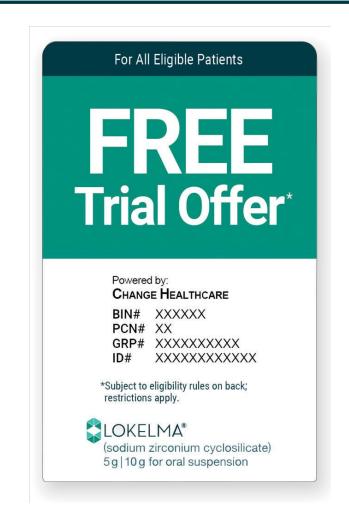
### LOKELMA IS THE #1 PRESCRIBED BRANDED K+ BINDER1

#### LOKELMA IS COVERED\* FOR 87% OF COMMERCIAL AND MEDICARE PART D PATIENTS.<sup>†2</sup>

**Complete Suite of Access and Affordability Services** 



- Assistance with understanding patient insurance coverage
- Prior authorization, claims, and appeal process support



- ► Free trial offer for all eligible patients<sup>‡</sup>
- Covers up to a 30-packet supply of LOKELMA



- Savings card for commercial patients§
- Reduces eligible patients' out-of-pocket costs to as low as \$0 for up to 1 year

Individual costs and benefit design may vary by plan. Please consult with individual plans for specific information. AstraZeneca does not endorse any Commercial, Medicare Part D, or Medicaid plan or plans. 

‡Subject to eligibility rules. Restrictions apply.

§For commercially insured patients. Subject to eligibility. Restrictions apply.

**References: 1.** Data on file, US-41202, AZPLP. **2.** Formulary Data are provided by Fingertip Formulary® and are current as of 11/16/20.

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<sup>\*&</sup>quot;Covered" is defined as any coverage level, specifically Tiers 1–7 and the \$0 Co-pay Tier, regardless of restrictions.

<sup>&</sup>lt;sup>†</sup> Patients" is defined as covered lives Commercial, EGWP, Employer, Fed Prog, FEHBP, Medicare MA, Medicare PDP, Medicare SN, Medi-Medi, Municipal Plan, PACE, PBM, Union, at

Tiers 1-7 in the nation, as calculated by Fingertip Formulary® as of 11/16/20.

### IMPORTANT SAFETY INFORMATION

#### 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.
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**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.

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

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**SAFETY** 

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### REFERENCES

- 1. LOKELMA® (sodium zirconium cyclosilicate) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2020.
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Abbreviations: chronic=not acute; CV=cardiovascular; DOPPS=Dialysis Outcomes and Practice Patterns Study; EOT=end of treatment; ESRD=end-stage renal disease; GI=gastrointestinal; HD=hemodialysis; IDWG=interdialytic weight gain; K+=potassium; LIDI=long interdialytic interval; qod=every other day; SAEs=serious adverse events; SD=standard deviation; SIDI=short interdialytic interval; USRDS=United States Renal Data System.

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HYPERKALEMIA RECURRENCE AND RISK

PATIENT PROFILE

MOA

**EFFICACY** 

**SAFETY** 

DOSING

**ACCESS** 

ISI

**REFERENCES** 

WHEN TREATING HYPERKALEMIA

CHOOSE THE PATH TO SUSTAINED\* K\* CONTROL¹

LOKELMA is the only FDA-approved
K<sup>+</sup> binder with efficacy and safety results
in the label for adult patients with
hyperkalemia on chronic hemodialysis<sup>1</sup>



SIGNIFICANT RESPONSE

**SUSTAINED\*** 

GENERALLY WELL TOLERATED

41% of patients treated with LOKELMA achieved the primary endpoint<sup>†</sup> compared to 1% of patients in the placebo group (*P*<0.001)<sup>1</sup>

LOKELMA sustained lower pre-dialysis K<sup>+</sup> levels in patients on hemodialysis with continued treatment<sup>1</sup>

A safety profile that is comparable to placebo<sup>1</sup>



For your patients, AstraZeneca offers the My LOKELMA Support Program to ensure access and affordability of LOKELMA

In Study 4, the safety of LOKELMA was comparable to placebo. Overall, 40 patients in the LOKELMA group (41.7%) reported adverse events, compared to 46 patients in the placebo group (46.5%). While 5% of patients developed pre-dialysis hypokalemia (serum K<sup>+</sup> <3.5 mEq/L) in both the LOKELMA and placebo groups, 3% and 1% of patients developed a serum K<sup>+</sup> <3.0 mEq/L in the LOKELMA and placebo groups, respectively. 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.<sup>17</sup>

\*Study 4 was an 8-week study (4-week titration period and 4-week evaluation period) in which patients received LOKELMA or placebo on non-dialysis days.¹

†Study 4 met its primary endpoint of a proportion of patients classified as responders, defined as patients who maintained a pre-dialysis serum K⁺ between 4.0-5.0 mEq/L on at least 3 out of 4 dialysis treatments after the long interdialytic interval and who did not receive rescue therapy during the evaluation period. Rescue therapy was defined as any urgent therapeutic intervention considered necessary to reduce serum K⁺ in the setting of severe hyperkalemia (defined as >6.0 mEq/L).¹¹

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You are encouraged to report negative side effects of AstraZeneca prescription drugs by calling 1-800-236-9933. If you prefer to report these to the FDA, either visit www.FDA.gov/medwatch or call 1-800-FDA-1088.



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**SUMMARY** 

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