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Compatibility study of patiromer with juices/liquids and soft foods

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Abstract

Patiromer powder for oral suspension (patiromer o.s.) is a once-daily, potassium (K^+) binder approved for the treatment of hyperkalemia. It is known that patiromer o.s. can be mixed with water, apple juice, or cranberry juice. This in vitro study assessed whether mixing patiromer o.s. with a variety of other liquids and soft foods would affect the total K^+-exchange capacity (TKEC) of patiromer. Juices (grape, orange, pear, or pineapple), nectars (apricot or peach), and other liquids/soft foods (milk, thickener, apple sauce, chocolate pudding, vanilla pudding, or yoghurt) were assessed for compatibility with patiromer o.s. at low and high ratio levels, equivalent to patiromer active moiety doses of 8.4 g and 25.2 g per 80 mL (1/3 cup), respectively. Mixtures were stirred, rested for 45 min, diluted with water, and centrifuged. Residues were washed, vacuum filtered, and dried. TKEC of the residue was evaluated; the prespecified acceptance criterion for patiromer was 8.4–10.0 mmol/g. Mean TKECs of the patiromer in juices/nectars were 8.7–8.9 mmol/g for the low ratio and 8.5–8.6 mmol/g for the high ratio. For other liquids/soft foods, the mean TKEC for patiromer at low and high ratios was 8.5–8.7 mmol/g. All tested vehicles were within the prespecified range. Mixing of patiromer o.s. with juices/liquids and soft foods does not adversely affect the K^+-binding capability of patiromer. Use of different vehicles for suspending patiromer o.s. may help with its palatability, enhance patient experience, and reduce nonadherence.

Keywords Patiromer, Food compatibility, Total potassium-exchange capacity, Potassium-binding capacity, Stability

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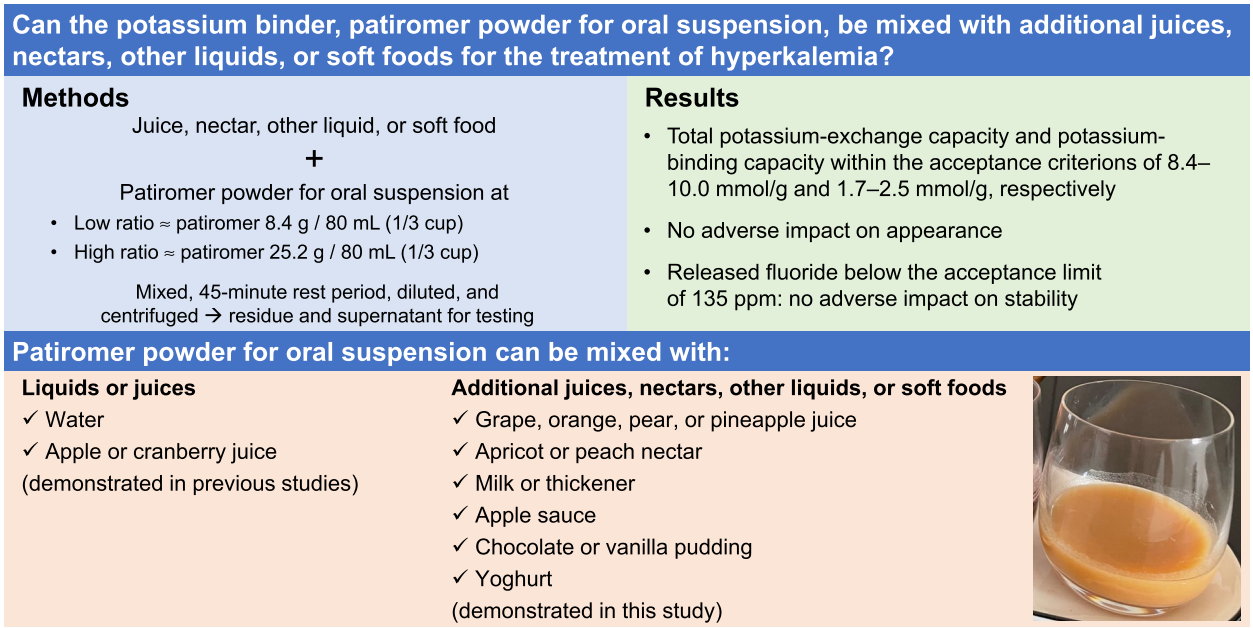
Graphical Abstract

The potassium binder, patiromer powder for oral suspension, can be mixed with water, juices (apple, cranberry, grape, orange, pear, or pineapple), nectar (apricot or peach), other liquids (milk or thickener), and soft foods (apple sauce, chocolate or vanilla pudding, or yoghurt) for the treatment of hyperkalemia.



Introduction

Patiromer powder for oral suspension (patiromer o.s.) is a once-daily non-absorbed polymer of patiromer sorbitex calcium spherical beads that acts as a potassium (K^+) binder in the gastrointestinal tract before being removed in the feces (Li et al. 2016). Patiromer o.s. is approved for treatment of hyperkalemia in adults (Vifor Pharma 2021, Vifor Pharma 2022). Patiromer o.s. is tasteless and odorless and was initially approved for oral administration suspended in 80 mL (1/3 cup) of water (Vifor Pharma 2021, Vifor Pharma 2022). As it was previously shown that there was no adverse impact on in vitro total K^+-exchange capacity (TKEC) when patiromer o.s. was mixed with apple juice or cranberry juice (Fogli et al. 2018), both the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) approved the use of apple or cranberry juice as alternative suspension vehicles (Vifor Pharma 2021, Vifor Pharma 2022). Since patients may prefer to take patiromer o.s. with alternative liquids or soft foods, the ability to mix it with small amounts of various liquids or soft foods may improve palatability and medication adherence. This in vitro study assessed the compatibility of patiromer o.s. with six different juices and nectars (grape juice, orange juice, pear juice, pineapple juice, apricot nectar, or peach nectar) and six other liquids/soft foods (milk, thickener, apple sauce, chocolate pudding, vanilla pudding, or yoghurt).

Materials and methods

Materials

Patiromer o.s., lot CGFYW, was used for all tests. Juices (grape, orange, pear, or pineapple), milk, apple sauce, and yoghurt were obtained from Migros or Coop in Switzerland. Nectars (apricot and peach), Thick-It thickener and Jell-O puddings (chocolate and vanilla) were obtained from online distributors Brack and Desertcart.

Sample preparation

The compatibility of patiromer with liquids and soft foods was assessed at two ratios, in line with the currently approved dosing of patiromer (Vifor Pharma 2021, Vifor Pharma 2022). Approximately half the weight of patiromer o.s. (excluding the suspending agent, which makes up 0.7% of the weight) is from the patiromer active moiety; therefore, for the low-level ratio, 8.5-g patiromer o.s. was mixed with 40 mL of vehicle (~ 1/6 cup), which is equivalent to a patiromer active moiety dose of 8.4 g per

80 mL (1/3 cup) of vehicle. For the high-level ratio, 12.7-g patiromer o.s. was mixed with 20 mL of vehicle (~ 1/12 cup), which is equivalent to a patiromer active moiety dose of 25.2 g per 80 mL (1/3 cup) of vehicle. Samples were prepared in triplicate.

For juices and nectars, the suspension was stirred for 5 min at medium speed with a magnetic stirrer; for other liquids and soft foods, the suspension was stirred with a spoon for 30 s (Fig. 1). Juices, nectars, other liquids, and soft foods were rested for 45 min. For juices and nectars, the suspension was diluted to 50 mL in purified water (water R); for other liquids and soft foods, the suspension was diluted to 100-mL purified water. Suspensions were shaken before centrifugation at 117 g for 30 s (centrifuge 5430R, Eppendorf). The supernatant was then transferred into a separate plastic vial. The remaining residue was washed six times with 50-mL purified water and vacuum filtered. TKEC, K^+-binding capacity (KBC), and microscopic appearance were determined from the residue. Fluoride concentration was determined in the supernatant to assess patiromer's stability.

Total potassium-exchange capacity

Approximately 3 g of prepared sample residue was weighed into a 50-mL centrifugation vial, 40 mL of 1N hydrochloric acid (HCl) was added, and the suspension was incubated for 20 min under shaking. The suspension was centrifuged for 1 min at 470 g (centrifuge 5430R, Eppendorf), and the supernatant was removed. This was repeated once more with 40 mL of 1N HCl. The remaining solid residue was washed a minimum of five times with 40 mL of purified water until the pH of the supernatant was neutral. The solid residue was filtered and dried at 130 °C for 2 h, and 50 mg of dried sample was weighed into a plastic vial; 25 mL of K-start solution (prepared by diluting 50 mL of 1N potassium hydroxide [KOH; Merck] to 1000 mL with purified water to give a 50 mmol/L solution) was added, and the suspension was incubated for 2 h under shaking. The suspension was filtered, diluted, and analyzed by ion chromatography with conductivity detection (ICS-3000, Dionex). The chromatographic separation was achieved on a CS12A column (250×4 mm, Dionex) with guard column CG12A (50×4 mm, Dionex). The eluent was 20-mM methanesulfonic acid at a flow rate of 1.0 mL/min. The oven temperature was set at 35 °C. Under these conditions, potassium elutes at approximately 5 min. The suppressor (CSRS300, Dionex) was regenerated with water R.

The K^+ concentration in mM for the K-start and sample solutions was determined by linear regression. The TKEC was determined from the difference of these solutions, referring to the weighed sample amount. The prespecified acceptance criterion was 8.4–10.0 mmol/g based on the commercial limits for TKEC (Australian Government Department of Health Therapeutic Goods Administration 2019).

Potassium-binding capacity

Approximately 450 mg of prepared sample residue was weighed into a 20-mL centrifugation vial, 10 mL of K-start solution (200 mmol/L) was added, and the suspension was incubated for 2 h under shaking. As per the TKEC method described in full above, the suspension was filtered, diluted, and analyzed by ion chromatography with suppressed conductivity detection (ICS-3000, Dionex).

The K^+ concentration in mM for the K-start and sample solutions was determined by linear regression. The KBC was determined from the difference in K^+ concentration of these solutions, referring to the weighed sample amount. The prespecified acceptance criterion was 1.7–2.5 mmol/g based on internal limits for KBC.

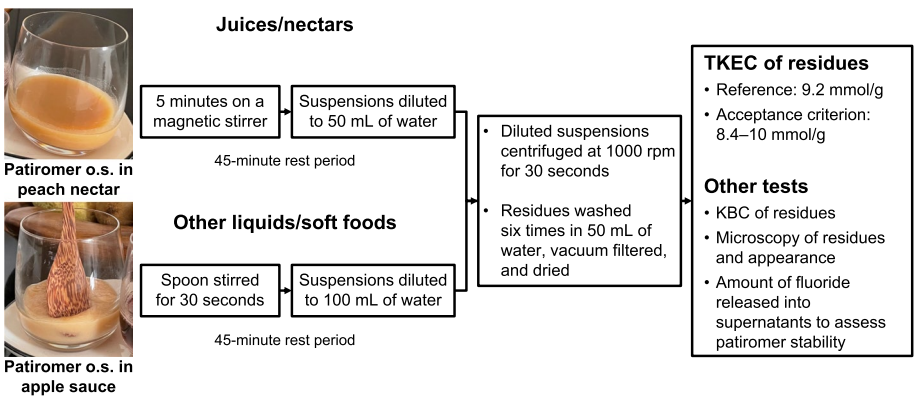


Fig. 1 Patiromer o.s. preparation and assessment. *KBC* Potassium-binding capacity, *Patiromer o.s.* Patiromer powder for oral suspension, *TKEC* Total potassium-exchange capacity

To understand the binding of K^+ from orange juice to patiromer, K^+ concentration was assessed in triplicate samples of untreated juice and supernatant from orange juice incubated with patiromer o.s. at low- and high-level ratios. The bound K^+ fraction was determined from the difference in K^+ concentration of samples of the supernatant and the untreated juice.

Fluoride

The chemical structure of patiromer contains fluorine (Li et al. 2016) and fluoride can be generated as a degradation product (Center for Drug Evaluation and Research 2015). The fluoride limit during the shelf-life of patiromer o.s. is in line with European Food Safety Authority (EFSA) recommendations for people ≥ 15 years old (patiromer o.s. is not indicated for children < 18 years old) (European Medicines Agency 2017, European Food Safety Authority 2005).

To assess patiromer's stability once mixed with vehicles, the fluoride concentration of the supernatant from prepared samples was determined. The pH of the supernatant from prepared samples was adjusted to be within pH 3–7. Four calibration standards in the range 0.1–10 mg fluoride/L were prepared from a 1000 mg/L fluoride solution (Merck). Potentials of sample and standard solutions were measured after addition of 5.0 mL of total ionic strength adjustment buffer II (Thermo Scientific) and thorough mixing with an ion-selective electrode (Orion™ Fluoride Electrode, Thermo Scientific).

The concentration of fluoride was determined from a fluoride calibration curve by preparing a semilogarithmic plot of concentration on the *x*-axis and potential on the *y*-axis. The prespecified acceptance limit was not more than 135 parts per million (ppm) based on the commercial limits for fluoride (the EFSA recommends the tolerable upper intake level for fluoride is 7 mg/day in people ≥ 15 years old (European Food Safety Authority 2005)).

Appearance and microscopy

Appearance of patiromer o.s. mixed with juices, nectars, other liquids, and soft foods was assessed visually using Pantone cards. Microscopic images of prepared sample residues were obtained after incubation of patiromer o.s. with vehicles at low and high ratios using an Axio Microscope (Zeiss, Germany).

Results

Mean TKEC for patiromer o.s. mixed with juices and nectars was 8.7–8.9 mmol/g for the low ratio and 8.5–8.6 mmol/g for the high ratio (Table 1). Mean TKEC for patiromer o.s. mixed with other liquids and soft foods was 8.5–8.7 mmol/g for both the low and high ratio (Table 1). Mean TKEC for the juices, nectars, other liquids, and soft foods was, therefore, within the prespecified acceptance criterion of 8.4–10.0 mmol/g. Mean KBC results were consistent with TKEC and were within the prespecified acceptance criterion of 1.7–2.5 mmol/g.

Table 1 Mean TKEC for patiromer o.s. mixed with juices/nectars and other liquids/soft foods

Vehicle	TKEC, mmol/g			
	Low ratio	RSD, %	High ratio	RSD, %
Juices/nectars				
Grape juice	8.8	2.0	8.6	0.8
Orange juice	8.8	2.0	8.5	0.7
Pear juice	8.7	1.6	8.5	0.4
Pineapple juice	8.9	1.5	8.5	0.8
Apricot nectar	8.8	0.4	8.6	0.5
Peach nectar	8.7	0.7	8.5	0.5
Other liquids/soft foods				
Milk	8.6	0.9	8.5	1.2
Thickener	8.6	0.4	8.6	0.6
Apple sauce	8.6	0.9	8.7	1.6
Chocolate pudding	8.5	0.8	8.6	0.7
Vanilla pudding	8.5	1.2	8.6	0.6
Yoghurt	8.7	0.4	8.6	0.4

The low and high ratios are equivalent to patiromer active moiety doses of 8.4 g and 25.2 g per 80 mL (1/3 cup) of vehicle, respectively

Patiromer o.s. Patiromer powder for oral suspension, *RSD* Relative standard deviation, *TKEC* Total potassium-exchange capacity

Binding of K^+ from orange juice to patiromer at low and high ratios was assessed when patiromer o.s. was mixed with orange juice. At low and high patiromer ratios, respectively, 70% and 84% of the K^+ in the orange juice was bound to patiromer, and only 10% and 5% of the relative KBC of patiromer had been used (Table 2).

The lot of patiromer o.s. used for these tests was light orange. For the samples of patiromer o.s. exposed to milk, chocolate pudding, and vanilla pudding, no visible changes of light orange were detected. Exposure of patiromer o.s. to orange juice, pear juice, pineapple juice, apricot nectar, peach nectar, thickener, apple sauce, or yoghurt resulted in a color change to light yellow, and light violet was detectable after exposure of patiromer o.s. to grape juice. Patiromer o.s. prepared in peach nectar or apple sauce are shown in Fig. 1 and in grape juice or milk are shown in Fig. 2. No visible alteration of patiromer o.s. spherical beads in juices, nectars, other liquids, and soft foods was detected by microscopy (Fig. 2).

The amount of fluoride released into supernatants was determined to assess patiromer's stability. Mean fluoride concentration in juices, nectars, other liquids, and soft foods was 5.5–22.8 ppm (Table 3). The fluoride

Table 2 Binding of K^+ from orange juice to patiromer o.s

	Untreated orange juice	Post-incubation of orange juice with patiromer o.s			
		Supernatant (unbound K^+)		Residue (patiromer o.s. bound K^+)	
		Low ratio	High ratio	Low ratio	High ratio
K^+, mg/L	2040	607	318	–	–
KBC, mmol/g	–	0.2	0.1	1.9	2.0
Relative KBC, %	–	70[a]	84[a]	10[b]	5[b]

[a] Calculated as a relative percentage from the difference in the K^+ concentrations of the untreated orange juice and the supernatant

[b] Calculated as a relative percentage of the KBC values of the supernatant and the total (the KBC values of the supernatant plus the residue determined in a K-start solution of 200 mM)

The low and high ratios are equivalent to patiromer active moiety doses of 8.4 g and 25.2 g per 80 mL (1/3 cup) of vehicle, respectively

K^+ Potassium, *KBC* K^+-binding capacity, *patiromer o.s.* Patiromer powder for oral suspension

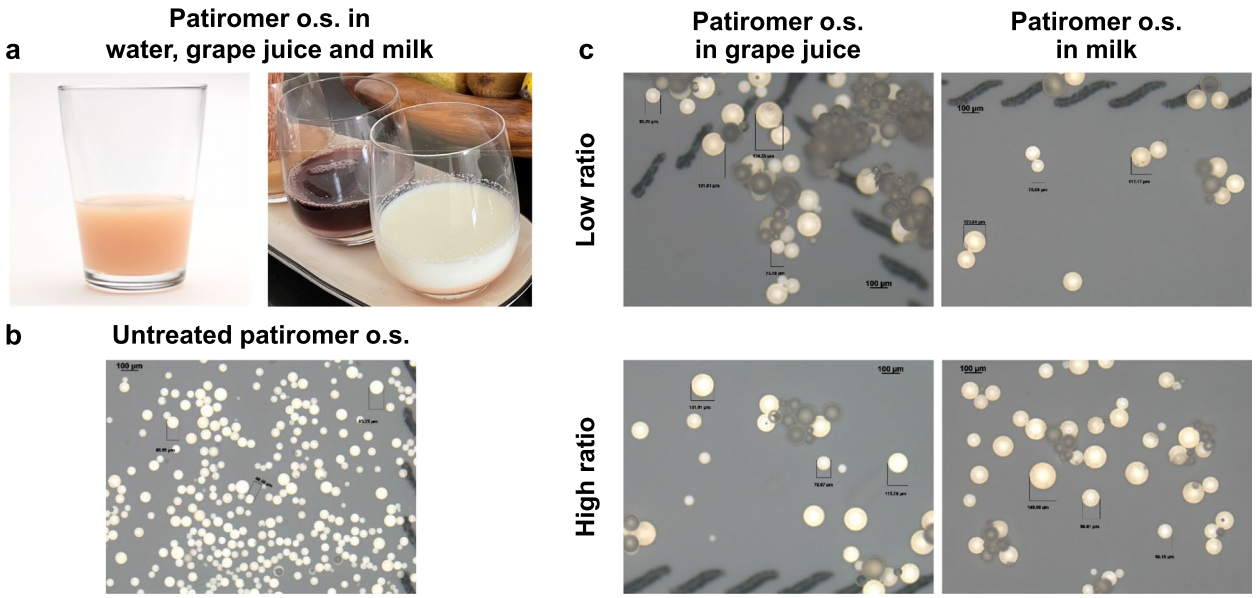


Fig. 2 **a** Appearance of patiromer o.s. in vehicles, **b** microscopy of untreated patiromer o.s., and **c** microscopy of patiromer o.s. at low and high ratios in grape juice and milk. The low and high ratios are equivalent to patiromer active moiety doses of 8.4 g and 25.2 g per 80 mL (1/3 cup) of vehicle, respectively. *Patiromer o.s.* Patiromer powder for oral suspension

concentrations are below the prespecified acceptance limit of not more than 135 ppm.

Discussion

It was previously shown that there was no adverse impact on in vitro TKEC when patiromer o.s. was mixed with apple juice or cranberry juice (Fogli et al. 2018). The current study showed that mixing of patiromer o.s. with an additional number of juices, nectars, other liquids, and soft foods does not adversely affect the patiromer's TKEC, KBC, appearance, or stability. On the basis of the findings of this study, both the EMA and FDA have approved the expanded use of liquids or soft foods (e.g., grape juice, orange juice, pear juice, pineapple juice, apricot nectar, peach nectar, milk, thickener, apple sauce, chocolate pudding, vanilla pudding, or yoghurt) in addition to apple juice and cranberry juice as alternative suspension vehicles (Vifor Pharma 2021, Vifor Pharma 2022).

The recommended dietary K^+ intake is 4.7 g/day for the general population, individuals with normal kidney function (estimated glomerular filtration rate [eGFR] $\geq$ 60 mL/min/1.73 m^2), no proteinuria but at risk of chronic kidney disease (CKD, e.g. diabetes), and individuals with mild-moderate CKD (*eGFR* 30 to < 60 mL/min/1.73 m^2) with proteinuria < 0.3 g/day (if no frequent/severe hyperkalemia) (Cupisti et al. 2018). For individuals with advanced CKD (*eGFR* < 30 mL/min/1.73 m^2) or any

Table 3 Mean amount of fluoride released from patiromer o.s. mixed with juices/nectars and other liquids/soft foods

Vehicle	Mean fluoride, ppm	
	Low ratio	High ratio
Juices/nectars		
Grape juice	9.2	5.6
Orange juice	10.5	6.0
Pear juice	9.3	6.0
Pineapple juice	9.6	5.5
Apricot nectar	10.8	6.2
Peach nectar	10.5	6.0
Other liquids/soft foods		
Milk	10.5	8.4
Thickener	14.0	10.2
Apple sauce	13.1	7.7
Chocolate pudding	22.8	12.2
Vanilla pudding	19.1	13.8
Yoghurt	10.7	6.0

The low and high ratios are equivalent to patiromer active moiety doses of 8.4 g and 25.2 g per 80 mL (1/3 cup) of vehicle, respectively

Patiromer o.s. Patiromer powder for oral suspension; *ppm* Parts per million

Table 4 Typical K^+ content of juices/nectars and other liquids/soft foods (University of Michigan Health 2016; Eat this much 2022; Kent Precision Foods Group 2022; HEB 2022)

Vehicle	K^+ content per 80 mL, mg (mEq)
Juices/nectars	
Grape juice (University of Michigan Health 2016)	115 (2.9)
Orange juice (University of Michigan Health 2016)	159 (4.1)
Pear juice (University of Michigan Health 2016)	24 (0.6)
Pineapple juice (University of Michigan Health 2016)	112 (2.9)
Apricot nectar (Eat this much 2022)	88 (2.3)
Peach nectar (University of Michigan Health 2016)	34 (0.9)
Soft foods/other liquids	
Milk (low fat) (University of Michigan Health 2016)	123 (3.2)
Thickener (in water) (Kent Precision Foods Group 2022)	0.7 (0.02)
Apple sauce (University of Michigan Health 2016)	61 (1.6)
Chocolate pudding (in low-fat milk) (University of Michigan Health 2016; HEB 2022)	123 (3.2)
Vanilla pudding (in low-fat milk) (University of Michigan Health 2016; HEB 2022)	123 (3.2)
Yoghurt (plain, whole milk) (Eat this much 2022)	128 (3.3)

K^+ potassium

CKD with proteinuria > 0.3 g/day (if hyperkalemia with high-fiber intake), and individuals on prevalent dialysis therapy or any CKD stage with existing or imminent protein-energy wasting (with high-fiber intake), the recommended dietary K^+ intake is < 3 g/day (Cupisti et al. 2018). The K^+ content of liquids or soft foods used to prepare the mixture should be considered as part of the dietary recommendations on K^+ intake for each individual patient (Table 4) (Vifor Pharma 2021, Vifor Pharma 2022).

Orange juice has the highest concentration of K^+ of the juices, nectars, other liquids, and soft foods evaluated, with 159 mg of K^+ per 80 mL of orange juice (University of Michigan Health 2016). We observed that a large proportion of the K^+ in the orange juice was bound to patiromer (70–84% depending on the ratio level), and the relative KBC of patiromer was only reduced by a small amount (5–10% depending on the ratio level); this suggested that the K^+ in the orange juice would have a limited impact on the efficacy of patiromer and, furthermore, could potentially attenuate the intestinal absorption of K^+ from the orange juice.

The results also show that the vehicles evaluated did not impact the stability of patiromer since fluoride concentrations with all vehicles remained below the prespecified acceptance limit. Mean fluoride concentrations in juices, nectars, other liquids, and soft foods were 5.5–22.8 ppm, which is less than 40 ppm stated on patiromer's certificate of analysis that was previously determined in 0.25 N HCl for 2 h. However, juices, nectars, other liquids, and soft foods are expected to be less acidic (in the range of pH 3–7) than 0.25 N HCl after a 45-min exposure to the vehicle, which will have impacted the results.

A key limitation of this study is that it was conducted in vitro; however, in a previous clinical study evaluating the effect of food on patiromer's ability to lower serum potassium in patients with hyperkalemia, patiromer was found to be equally effective at potassium lowering when taken with food or without food (Pergola et al. 2017). Considered together with the data from the current study, the juices, nectars, other liquids, and soft foods tested are not expected to impact patiromer's potassium-lowering effect in vivo. Additionally, since this was an in vitro study, palatability was not assessed. However, palatability of patiromer in water has previously been studied, with 90% of healthy volunteers reporting positive palatability experiences with patiromer in terms of odor or taste (Brenner et al. 2016). The choice of different vehicles to take patiromer o.s. may help with its palatability and enhance patient experience.

Conclusion

Mixing of patiromer o.s. with small amounts of juices, nectars, other liquids, and soft foods does not adversely affect the drug's capacity to bind to K^+ or its stability. Use

of different vehicles to take patiromer o.s. may help with its palatability, enhance patient experience, and reduce the risk of nonadherence.

Abbreviations

CKD	Chronic kidney disease
EFSA	European Food Safety Authority
eGFR	Estimated glomerular filtration rate
EMA	European Medicines Agency
FDA	US Food and Drug Administration
HCl	Hydrochloric acid
K^+	Potassium
KBC	K^+-binding capacity
KOH	Potassium hydroxide
Patiromer o.s.	Patiromer powder for oral suspension
ppm	Parts per million
RSD	Relative standard deviation
TKEC	Total K^+-exchange capacity

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Authors' contributions
All authors contributed to the study concept and design. MK organized the study, supervised the laboratory experiments, checked and interpreted the results, and provided the first draft of the manuscript. MW interpreted the results and reviewed and adapted the first draft of the manuscript. CPMQ and LL reviewed and provided feedback on the first draft of the manuscript. All authors commented on subsequent drafts of the manuscript and approved the final version.

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Availability of data and materials
All data generated or analyzed during this study are included in this published article.

Declarations

Competing interests
M. K., M. W., L. L., and C. P. M. Q. are employees of CSL Vifor.

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