

1. NAME OF THE MEDICINAL PRODUCT

Veltassa 8.4 g powder for oral suspension
Veltassa 16.8 g powder for oral suspension
Veltassa 25.2 g powder for oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 8.4 g patiomer (as patiomer sorbitex calcium)
Each sachet contains 16.8 g patiomer (as patiomer sorbitex calcium)
Each sachet contains 25.2 g patiomer (as patiomer sorbitex calcium)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral suspension.
Off-white to light-brown powder, occasionally containing white particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Veltassa is indicated for the treatment of hyperkalaemia in adults.

4.2 Posology and method of administration

Posology

Starting dose

The recommended starting dose is at least 8.4 g patiomer once a day.

In general, administration of Veltassa should be separated by 3 hours from other oral medicinal products. Separation is not needed for certain medicinal products (see section 4.5).

Because of delayed onset of action, Veltassa should not replace emergency treatment for life-threatening hyperkalaemia.

Dose adjustment and maintenance dose

The daily dose of Veltassa should be adjusted based on potassium level and desired target range. The daily dose may be increased or decreased by intervals of one week in increments of 8.4 g as needed to reach the desired target range, up to a maximum daily dose of 25.2 g. If the potassium level falls below the desired range, administration of Veltassa should be reduced or discontinued.

If a dose of Veltassa is forgotten, the forgotten dose should be taken as soon as possible on the same day. The forgotten dose should not be taken with the following dose.

Method of administration

Oral use.

Veltassa should be mixed with water until a uniform consistency is achieved, according to the following steps:

The entire dose of Veltassa should be first mixed with approximately 40 mL of water (3 tablespoons) in a glass. Then add approximately 40 mL of water and carefully mix the suspension. The powder will not dissolve. If necessary, water can be added to the mixture to obtain the desired consistency.

The mixture should be consumed immediately. If powder remains in the glass after consuming the mixture, add water, mix and drink immediately. Repeat if necessary to guarantee administration of the entire dose.

The following liquids or soft foods can be used instead of water to prepare the mixture by following the same steps as described above: apple juice, cranberry juice, pineapple juice, orange juice, grape juice, pear juice, apricot nectar, peach nectar, yoghurt, milk, thickener, apple sauce, vanilla and chocolate pudding.

The potassium content of liquids or soft foods used to prepare the mixture should be considered as part of the dietary recommendations on potassium intake for each individual patient.

Veltassa can be taken with or without food. It should not be heated (for example in a microwave) or added to hot food or beverages. Veltassa should not be taken in its dry form.

Dialysis patients

There is only limited data available on the use of Veltassa in dialysis patients. No specific guidelines for dose and administration were applied to these six patients during clinical studies.

Elderly patients

Among the total number of patients treated with Veltassa during clinical trials, 398 (59.8%) patients were 65 years and older, and of these patients, 132 (19.8%) were 75 years and older. No specific dose guidelines were applied in these patients during these studies.

Children and adolescents

The safety and efficacy of Veltassa in children and adolescents aged up to 18 years have not yet been established. No data are available.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Hypomagnesaemia

Patiromer may cause hypomagnesaemia by binding magnesium in the colon. In clinical studies, magnesium levels <1.4 mg/dL were observed in 9% of patients treated with Veltassa, with no patients developing magnesium levels <1.0 mg/dL. Mean reductions in magnesium level occurred at the start of treatment with Veltassa and were ≤ 0.17 mg/dL throughout the entire course of treatment. Magnesium levels must be monitored for one month after initiating treatment with Veltassa and monitoring should be continued in the event of decreased serum levels of magnesium. Magnesium supplementation should be planned in patients who develop hypomagnesaemia during treatment with Veltassa.

Gastrointestinal disorders

Patients with a history of intestinal blockage or major digestive surgery, diabetic gastroparesis, presenting severe gastrointestinal disorders or swallowing disorders were not included in the clinical studies. Treatment with Veltassa should be avoided in these patients.

Discontinuation of treatment with Veltassa

Potassium levels may increase upon discontinuation of treatment with Veltassa, particularly in cases where treatment is followed by a renin angiotensin aldosterone system (RAAS) inhibitor. Patients should be informed that they must not discontinue treatment without consulting their doctor. Increases in potassium level may occur starting from the 2nd day after the last dose of Veltassa.

Serum potassium levels

Serum potassium should be monitored when clinically indicated, including after changes are made to medicinal products that affect the serum potassium concentration (e.g. RAAS inhibitors or diuretics) and after the Veltassa dose is titrated.

Sorbitol

Veltassa contains sorbitol. Patients presenting a hereditary intolerance to fructose should not take this medicinal product.

Fluoride

Veltassa contains fluoride. In patients presenting severe chronic renal insufficiency (CRI), all other sources of fluoride should be limited.

Information about calcium

Veltassa contains calcium as part of the counterion complex. Calcium is partially released some of which may be absorbed (see section 5.1). However, in clinical studies with durations up to one year, no meaningful changes in mean serum calcium levels were observed. The benefits and risks of administering this medicinal product should be carefully evaluated by the physician in at risk patients.

4.5 Interaction with other medicinal products and other forms of interaction

Veltassa has the potential to bind certain medicinal products co-administered by oral route, which may reduce their gastrointestinal absorption. As patiomer is not absorbed or metabolised by the body, there are limited effects on the function of other medicinal products.

Table 1 shows the medicinal products tested for interactions with Veltassa and recommendations for administration of these medicinal products with Veltassa. For oral medicinal products not listed, administration of patiomer should be separated by at least 3 hours as precautionary measure.

Table 1: Recommendations for administration of medicinal products tested for interactions with Veltassa

Medicinal product	Clinical recommendation	Basis for recommendation
Angiotensin-converting enzyme (ACE) inhibitors		
Benazepril, captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril	No separation from Veltassa required	In vitro: no interaction observed
Angiotensin II receptor blockers (ARB)		
Telmisartan	Separate by at least 3 hours from Veltassa	In vitro binding observed
Azilsartan, candesartan, irbesartan, losartan, olmesartan, valsartan	No separation from Veltassa required	In vitro: no interaction observed
β--adrenoceptor blockers (β-blocker)		
Bisoprolol, carvedilol, nebivolol	Separate by at least 3 hours from Veltassa	In vitro binding observed
Metoprolol	No separation from Veltassa required	In vivo: no interaction observed
Loop diuretics		
Furosemide	No separation from Veltassa required	In vivo: no interaction observed
Bumetanide, torasemide		In vitro: no interaction observed

Mineralocorticoid receptor antagonists (MRA)		
Eplerenone, finerenone, spironolactone	No separation from Veltassa required	In vitro: no interaction observed
Neprilysin inhibitors		
Sacubitril	No separation from Veltassa required	In vitro: no interaction observed
Sodium-glucose cotransporter-2 (SGLT-2) inhibitors		
Canagliflozin, dapagliflozin, empagliflozin	No separation from Veltassa required	In vitro: no interaction observed
Antibiotics		
Ciprofloxacin	Separate by at least 3 hours from Veltassa	In vivo interactions observed but not when separated by 3 hours
Trimethoprim	No separation from Veltassa required	In vivo: no interaction observed
Amoxicillin, cephalexin		In vitro: no interaction observed
Anticoagulants		
Warfarin	No separation from Veltassa required	In vivo: no interaction observed
Apixaban, rivaroxaban		In vitro: no interaction observed

Anti-Parathyroid Agents and Thyroid Preparations		
Levothyroxine	Separate by at least 3 hours from Veltassa	In vivo interactions observed but not when separated by 3 hours
Cinacalcet	No separation from Veltassa required	In vivo: no interaction observed
Antithrombotic Agents		
Clopidogrel	No separation from Veltassa required	In vivo: no interaction observed
Acetylsalicylic acid		In vitro: no interaction observed
Blood Glucose Lowering Drugs		
Metformin	Separate by at least 3 hours from Veltassa	In vivo interactions observed but not when separated by 3 hours
Glipizide	No separation from Veltassa required	In vitro: no interaction observed
Calcium Channel Blockers		
Amlodipine, verapamil	No separation from Veltassa required	In vivo: no interaction observed
Immunosuppressants		
Mycophenolate mofetil	Separate by at least 3 hours from Veltassa	In vitro binding observed
Tacrolimus	No separation from Veltassa required	In vitro: no interaction observed

Others		
Quinidine	Separate by at least 3 hours from Veltassa	In vitro binding observed
Lithium	No separation from Veltassa required	In vivo: no interaction observed
Allopurinol, atorvastatin, digoxin, phenytoin, riboflavin, sevelamer		In vitro: no interaction observed

Effect of Food

In an open-label study, 114 patients with hyperkalaemia were randomized to patiromer once daily with food or without food. Serum potassium at the end of treatment, the change from baseline in serum potassium, and the mean dose of patiromer were similar between groups.

4.6 Fertility, pregnancy and lactation

Pregnancy

To date, there are no clinical data regarding the use of Veltassa in pregnant women.

Animal studies have not shown any direct or indirect toxicity affecting pregnancy, embryonic development, foetal development and/or postnatal development (see section 5.3).

As a precautionary measure, it is preferable to avoid the use of Veltassa during pregnancy.

Breastfeeding

No effect on the breastfeeding newborn infant is expected since the systemic exposure to patiromer in breastfeeding woman is negligible. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from patiromer therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman.

Fertility

There are no data on the effect of patiromer on fertility in humans. Animal studies showed no effects on reproductive function or fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

Veltassa has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The safety profile of Veltassa is based on a total of 666 patients having participated in clinical studies: 547 patients presenting hyperkalaemia included in the treatment studies and 119 patients at risk of hyperkalaemia included in prevention studies.

The majority of the adverse reactions (AR) reported in these studies were gastrointestinal disorders, with the most frequently reported ARs being: constipation, diarrhoea, abdominal pain, flatulence, nausea, vomiting and hypomagnesaemia. Gastrointestinal disorders were generally of a mild to moderate intensity, did not appear to be dose-dependent, generally resolved spontaneously or with treatment and none were described as serious.

Tabulated list of adverse reactions

Adverse reactions are listed below by system organ class and by frequency.

Frequencies of undesirable effects: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$), not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ Class	Common ($\geq 1/100$ to $< 1/10$)	Uncommon ($\geq 1/1,000$ to $< 1/100$)
Metabolism and nutrition disorders	Hypomagnesaemia	
Gastrointestinal disorders	Constipation Diarrhoea Abdominal pain Flatulence	Nausea Vomiting

To report any side effect(s):

- The National Pharmacovigilance Centre (NPC):
 - SFDA Call Center: 19999
 - E-mail: npc.drug@sfd.gov.sa
 - Website: <https://ade.sfd.gov.sa/>

4.9 Overdose

Doses of Veltassa greater than 50.4 g of patiomer per day have not been studied. As excessive doses of Veltassa may result in hypokalaemia, serum potassium levels must be monitored. If medical proves necessary, appropriate measures to re-establish normal potassium levels should be undertaken.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for treatment of hyperkalaemia and hyperphosphataemia.

ATC code: V03AE09

Mechanism of action

Patiromer is a non-absorbed, cation exchange polymer that contains a calcium-sorbitol complex as a counterion.

Patiromer increases faecal potassium excretion through binding of potassium in the lumen of the gastrointestinal tract. The binding of potassium reduces the concentration of free potassium in the gastrointestinal lumen, which results in a reduction of serum potassium levels.

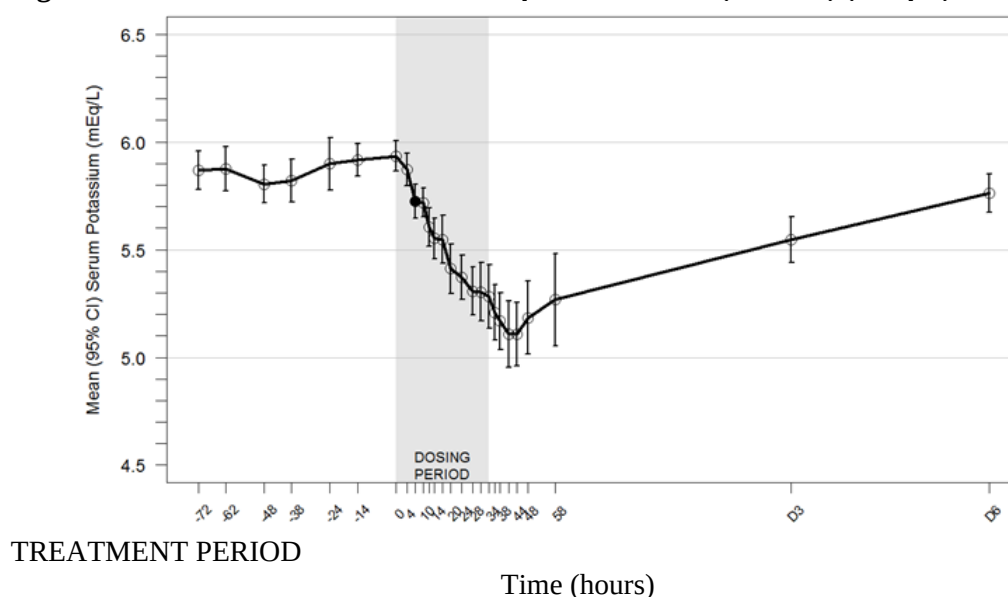
Pharmacodynamic effects

In a phase 1 study conducted in healthy adult volunteers (6-8 subjects per group), Veltassa (from 0 g to 50.4 g of patiromer daily) administered three times daily for 8 days induced a dose-dependent increase in faecal excretion of potassium. A corresponding dose-dependent decrease in kaliuresis without effect on serum potassium was also observed. Compared to placebo, Veltassa at doses of 25.2 g and 50.4 g daily significantly reduced mean daily kaliuresis.

In a phase 1, open label, repeat dose crossover study conducted among 12 healthy volunteers, the dose of 25.2 g of patiromer daily was orally administered following a schedule of once a day, twice a day or three times a day for 6 days according to a randomly assigned sequence. A significant increase in mean daily faecal excretion of potassium and a concomitant decrease in mean daily kaliuresis was observed with the three dosing schedules. The mean increase in faecal excretion of potassium was from 1,283 to 1,550 mg/day and mean decrease in kaliuresis was from 1,438 to 1,534 mg/day across the three dosage schedules. No significant difference was observed between the dosing schedules in terms of mean daily faecal and urinary excretion of potassium, either in the global comparison or paired comparison. Daily urinary excretion of calcium increased by 53 mg/day, 66 mg/day and 73 mg/day compared to baseline with the schedules once daily, twice daily and three times daily, respectively.

In a non-controlled, open-label study, 25 patients presenting with hyperkalaemia (mean baseline potassium level of 5.9 mEq/L) and chronic renal insufficiency followed a controlled potassium regimen for three days, then received 16.8 g of patiromer per day (in two fractionated doses) for two days, while continuing the controlled regimen. A statistically significant reduction in potassium levels (0.2 mEq/L) was observed 7 hours after the initial dose. Potassium levels continued to decline during the 48-hour treatment period (0.8 mEq/L 48 hours after initial dose). Potassium levels remained stable for 24 hours following the last dose, then increased during the 4-day observation period following discontinuation of Veltassa.

Figure 1: Onset of action – Mean potassium level (95% CI) (mEq/L) over time



* The full circle indicates the time at which the first statistically significant reduction was identified. A mean reduction of 0.8 mEq/L was observed at hour 48 ($p < 0.001$).

Comments: hours 72 to 0 = pre-screening period with controlled potassium regimen; hours 0 to 58 = period of treatment with Veltassa 16.8 g per day in fractionated doses in a hospital environment; hour 58 to day 6 = period of outpatient follow-up.

Clinical efficacy and safety

Randomised, single-blind, two-part withdrawal study in patients with chronic renal insufficiency (CRI) and hyperkalaemia receiving stable doses of at least one RAAS inhibitor.

The safety and efficacy of patiomer have been demonstrated in a randomised, single blind, two part withdrawal study evaluating this treatment in patients presenting CRI and hyperkalaemia receiving stable doses of at least one RAAS inhibitor (i.e. angiotensin converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB] or aldosterone antagonist [AA]).

In part A, 243 patients were treated with patiomer for 4 weeks. The initial dose of Veltassa was 8.4 g of patiomer daily (in fractionated doses) in patients with a potassium level from 5.1 mEq/L to <5.5 mEq/L (mmol/L) at baseline and 16.8 g of patiomer daily (in fractionated doses) in those with a potassium level from 5.5 mEq/L to <6.5 mEq/L at baseline. The dose was adjusted, as needed, on the basis of potassium level, determined starting from day 3 and then in bi-weekly visits (weeks 1, 2 and 3) to the end of the 4-week treatment period, for the purpose of maintaining potassium level within the target range (3.8 mEq/L to <5.1 mEq/L).

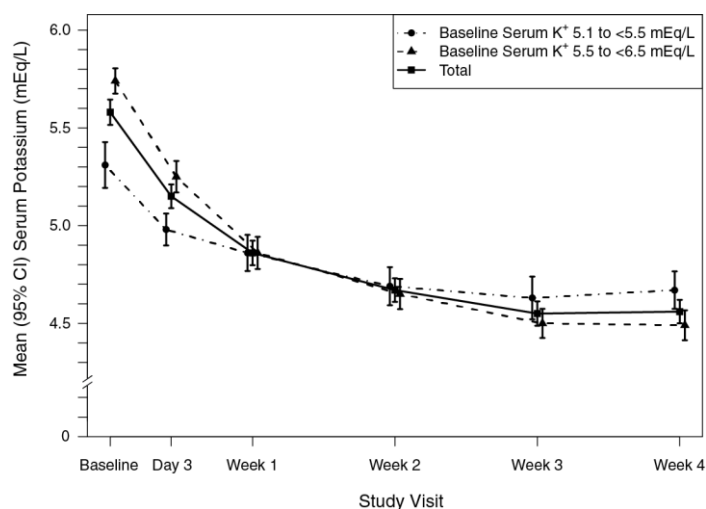
Mean patient age was 64 years, 58% of patients were male and 98% were of Caucasian origin. Approximately 97% of patients presented with hypertension, 57% with type 2 diabetes and 42% with heart failure.

Mean daily doses of patiomer were 13 g and 21 g in patients with potassium levels of 5.1 to <5.5 mEq/L and 5.5 to <6.5 mEq/L, respectively.

Mean potassium level was 5.58 mEq/L at baseline and the mean variation (SD) of potassium level between the baseline visit and week 4 of part A was 1.01 (0.031) mEq/L, 95% CI: [-1.07; -0.95] (see figure 2). This mean reduction of potassium level was statistically significant. For

the secondary endpoint of part A, 76% (95% CI: 70%, 81%) of patients had a potassium level in the target range of 3.8 mEq/L to <5.1 mEq/L at week 4 of part A.

Figure 2: Estimated mean (95% CI) potassium level (mEq/L) determined by the central laboratory over time



Baseline potassium level from 5.1 to <5.5 mEq/L

Baseline potassium level from 5.5 to <6.5 mEq/L

Total

Mean potassium level (95% CI) (mEq/L)

In Part B, 107 patients who had potassium levels from 5.5 mEq/L to <6.5 mEq/L at the baseline visit in part A, and whose potassium levels were within the target range (3.8 mEq/L to <5.1 mEq/L) at week 4 of part A and who were still receiving one or more RAAS inhibitors were randomised to continue treatment with patiromer or to receive placebo for 8 weeks in order to evaluate the effect of discontinuing patiromer on potassium levels. In the patients randomised to patiromer, the mean daily dose was 21 g at the start and during part B.

The primary endpoint in part B was the change in potassium level from inclusion in part B until the first visit during which the patient's potassium level for the first time fell outside of the range of 3.8 to <5.5 mEq/L or until week 4, if the patient's potassium level remained in this range. In part B, potassium levels increased by 0.72 mEq/L, 95%CI [0.46, 0.99] in patients receiving placebo, while showing no change in patients continuing treatment with patiromer.

The percentage of patients having presented a serum potassium level ≥ 5.1 mEq/L at any point in part B was higher in the group receiving placebo (91% [95% CI: 83%, 99%]) than in the group treated with patiromer (43% [95% CI: 30%, 56%]). The percentage of patients having presented a potassium level ≥ 5.1 mEq/L at any point in part B was higher in the group receiving placebo (60% [95% CI: 47%, 74%]) than in the group treated with patiromer (15% [95% CI: 6%, 24%]).

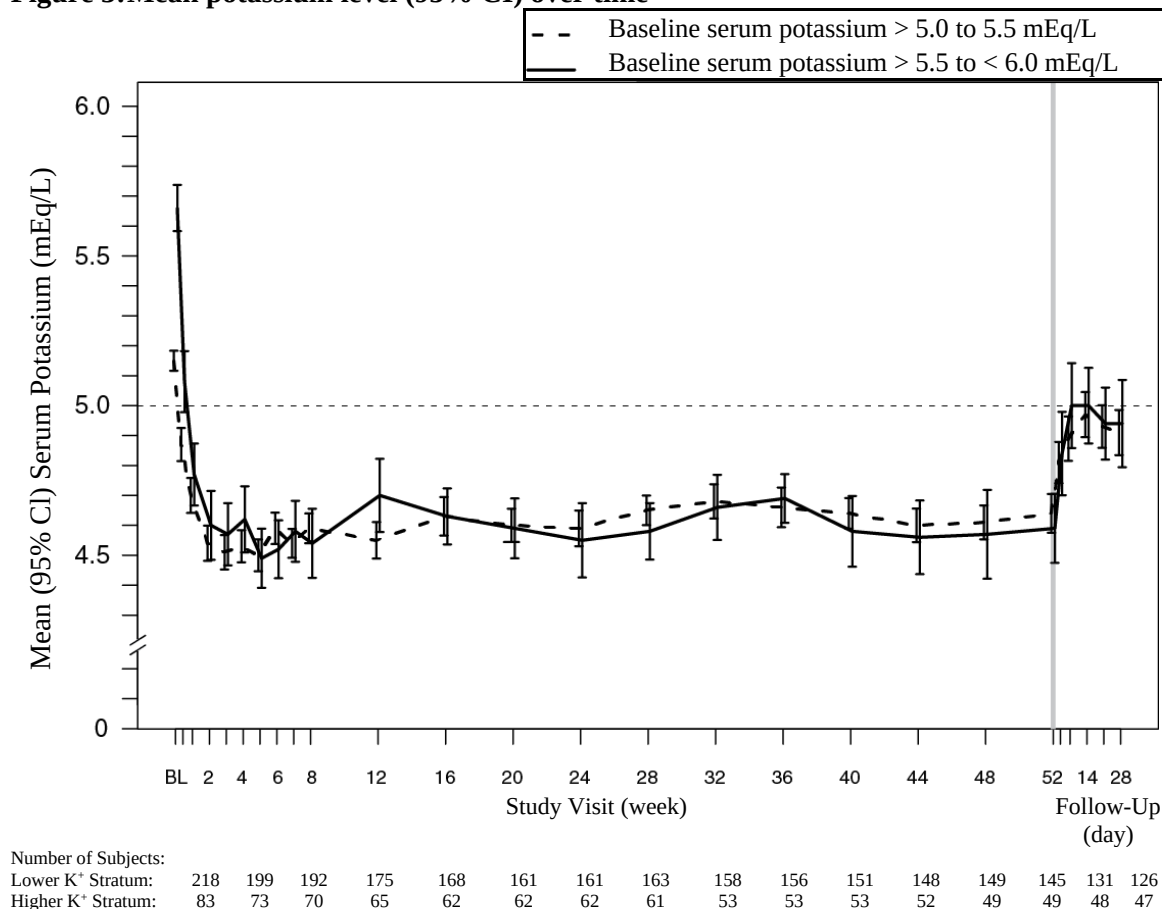
Fifty two percent (52%) of subjects receiving placebo needed to discontinue treatment with a RAAS inhibitor because of recurrence of hyperkalaemia *versus* 5% of subjects treated with patiromer.

Open-label study of up to 52 weeks in type 2 diabetes patients with CRI and hyperkalaemia receiving stable doses of a RAAS inhibitor

The effect of treatment with patiromer for a duration of up to 52 weeks was evaluated in an open label study of 304 hyperkalaemic patients with CRI and type 2 diabetes on stable doses of a RAAS inhibitor. Reductions in potassium levels observed during treatment with patiromer were maintained for one year with regular treatment. In patients with a baseline potassium level

of >5.0 to 5.5 mEq/L having already received an initial dose of 8.4 g patiromer per day (in fractionated doses), the mean daily dose was 14 g. In those with a baseline potassium level of >5.5 to <6.0 mEq/L having already received an initial dose of 16.8 g patiromer per day (in fractionated doses), the mean daily dose was 20 g during the entire study.

Figure 3: Mean potassium level (95% CI) over time



The ability of patiromer to enable concomitant spironolactone treatment was investigated in a randomised, double-blind, placebo-controlled study in heart failure patients who were clinically indicated to receive AA. Patients initiated spironolactone at 25 mg/day at the same time as their randomised treatment (patiromer 12.6 g BID or placebo), and were up-titrated to 50 mg/day after Day 14 if serum potassium was >3.5 and ≤5.1 mEq/L. Of the 105 patients who were randomised and received study treatment (patiromer 56; placebo 49), mean age was 68.3 years, 60.6% were men, 97.1% were Caucasian, and mean eGFR was 81.3 mL/min. Mean baseline serum potassium values were 4.71 mEq/L for patiromer and 4.68 mEq/L for placebo.

The primary efficacy endpoint, change from baseline in serum potassium to the end of the 28-day treatment period, was significantly lower ($p < 0.001$) in the patiromer group (LS mean [SEM]: -0.21 [0.07] mEq/L) as compared to the placebo group (LS mean [SEM]: +0.23 [0.07] mEq/L). There were also fewer patients in the patiromer group with serum potassium values >5.5 mEq/L (7.3% vs. 24.5%; $p = 0.027$) and more patients on spironolactone 50 mg/day (90.9% versus 73.5%, $p = 0.022$).

Double-blind 12-week study in patients receiving spironolactone treatment for treatment-resistant hypertension

Another randomised, double-blind, placebo-controlled study investigated the effect of patiromer on the tolerability of spironolactone treatment in patients with treatment-resistant hypertension and CRI. During the study, patients were randomised to receive patiromer or placebo in addition to spironolactone (25 mg/day; increased to 50 mg/day from week 3 in patients with a systolic blood pressure ≥120 mmHg and a serum potassium of ≤5.1 mEq/L). To maintain a serum

potassium level of between ≥ 4.0 mEq/L and ≤ 5.1 mEq/L, the patiromer/placebo dose could be increased on a weekly basis from the starting dose of 8.4 g/day to a maximum of 25.2 g/day.

A total of the 295 randomized patients (147 receiving patiromer; 148 receiving placebo) with a mean age of 68.1 years and a mean eGFR of 35.73 mL/min/1.73m² were randomised, stratified according to baseline serum potassium levels (mean serum potassium was 4.71 mEq/L in the patiromer arm and 4.68 mEq/L in the placebo control arm) and a history of diabetes mellitus (type 1 or type 2). The primary endpoint was the percentage of patients who continued spironolactone treatment until the end of the study (12 weeks). This percentage was significantly greater in the patiromer group than in the placebo group (85.7% *versus* 66.2%; $p < 0.0001$). Patients in the patiromer arm received a spironolactone dose of 50 mg/day more often (69.4% *versus* 51.4% in the placebo control arm) and their serum potassium levels were ≥ 5.5 mEq/L less often than patients in the placebo control arm (35.4% vs 64.2% in the placebo control; $p < 0.001$).

Overall, in the phase 2 and 3 clinical studies, 99.5% of patients were receiving RAAS inhibitor therapy at baseline, 87.0% had CRI with eGFR < 60 mL/min/1.73 m², 72.8% had diabetes mellitus and 47.5% had heart failure.

5.2 Pharmacokinetic properties

Absorption

Patiromer works by binding potassium in the gastrointestinal tract. Serum concentration is therefore not relevant for its efficacy. Because of the insolubility and non-absorption characteristics of this medicinal product, many classic pharmacokinetic studies have not been possible to conduct.

In ADME (absorption, distribution, metabolism and excretion) studies with radiolabelling conducted in rats and dogs, patiromer was not systemically absorbed.

Distribution

Quantitative whole-body autoradiography analysis in rats demonstrated that radioactivity was limited to the gastrointestinal tract, with no detectable level of radioactivity in any other tissues or organs.

Biotransformation

Not applicable, because of insolubility and non-absorption characteristics of Veltassa.

Elimination

In ADME studies with radiolabelling in rats and dogs, patiromer was excreted through the faeces.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, toxicity to reproduction and development.

Patiromer did not demonstrate genotoxic effects in the reverse mutation studies (Ames test), chromosomal or micronucleus aberrations in rats.

No carcinogenicity studies have been conducted.

Patiromer had no negative impact on fertility in male or female rats at doses of up to 10 times the recommended maximum daily dose in humans (RMDH). Patiromer did not have any harmful effects on embryonic or foetal development, either, when administered to pregnant rats at doses of up to 6 g/kg, thus providing a margin of exposure 12 times greater than the RMDH and administered to pregnant rabbits at doses of up to 3 g/kg, thus providing a margin of exposure 6 times greater than the RMDH.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xanthan gum

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store and transport refrigerated (2°C – 8°C). Avoid any exposure to temperatures above 40°C.

Once issued to the patient, Veltassa can be kept at room temperature (below 25°C) for a maximum of 6 months.

Do not use Veltassa after the expiry date printed on the sachet.

The mixture should be taken within 1 hour of initial suspension.

Keep out of the sight and reach of children.

6.5 Nature and contents of container

8.4 g, 16.8 g or 25.2 g of patiromer (in the form of patiromer sorbitex calcium), as powder in sachets made of five layers: polyethylene, aluminium, polyethylene, polyester and paper.

Pack sizes: box of 30 sachets.

Not all strengths may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Marketing Authorization Holder

Vifor Fresenius Medical Care Renal Pharma Ltd.
Rechenstrasse 37
9014 St. Gallen
Switzerland

Bulk manufacturing site
Corden Pharma Lisbon S.A.
R. da Indústria, 2
Quinta Grande
2610-088 Amadora
Portugal

Batch releasing site
Vifor (International) Inc.
Rechenstrasse 37
9014 St. Gallen
Switzerland

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 July 2017

9. DATE OF REVISION OF THE TEXT

January 2023