AUSTRALIAN PRODUCT INFORMATION – VELTASSA® (PATIROMER SORBITEX CALCIUM)

1 NAME OF THE MEDICINE

Patiromer sorbitex calcium

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of Veltassa powder for oral suspension contains 8.4 g, 16.8 g or 25.2 g of patiromer (as sorbitex calcium).

For the full list of excipients, see Section 6.1 List of excipients

3 PHARMACEUTICAL FORM

Veltassa powder for oral suspension is an off-white to light-brown powder, with occasional white particles.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Veltassa is indicated for the treatment of hyperkalaemia in adults.

4.2 DOSE AND METHOD OF ADMINISTRATION

Dose

The recommended starting dose of Veltassa is 8.4 g patiromer (as sorbitex calcium) once daily. Take the prepared Veltassa suspension with or without food and preferably at the same time each day.

Adjust the daily dose of Veltassa based on the serum potassium level and the desired target range. The daily dose may be increased at 1-week or longer intervals by increments of 8.4 g, or decreased by 8.4 g, as necessary to reach the desired target range, up to a maximum dose of 25.2 g daily. If serum potassium falls below the desired range, the dose should be reduced or discontinued.

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

Upon discontinuation of Veltassa, serum potassium levels may rise, especially if renin angiotensin aldosterone system (RAAS) inhibitor treatment is continued (see 4.4 Special warnings and precautions for use). Therefore, patients should consult their doctor before discontinuing this medication.

Administer Veltassa at least 3 hours before or 3 hours after other oral medications except those shown to not have a clinically important interaction (see 4.5 Interactions with other medicines and other forms of interactions).

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 (see **Monitoring**, 4.4 Special warnings and precautions for use).

Serum magnesium should be monitored for at least 1 month after initiation of patiromer treatment (see **Monitoring**, 4.4 Special warnings and precautions for use).

Serum calcium should be monitored in patients at risk of hypercalcaemia (see **Monitoring**, 4.4 Special warnings and precautions for use).

Method of administration

Veltassa should be mixed with water and stirred to a suspension of uniform consistency, according to the following steps:

Measure 80 mL of water. Pour half of the water into a glass, then add Veltassa and stir. Add the remaining half of the water and stir thoroughly. The powder will not dissolve and the mixture will look cloudy. Add more water to the mixture as needed for desired consistency.

Drink the mixture immediately. If powder remains in the glass after drinking, add more water, stir and drink immediately. Repeat as needed to ensure the entire dose is administered.

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.

Other liquids containing high amounts of potassium should be avoided.

Veltassa can be taken with or without food. Veltassa should not be heated (e.g., microwaved) or added to heated foods or liquids. Veltassa should not be taken in its dry form.

4.3 CONTRAINDICATIONS

The use of Veltassa is contraindicated in cases of hypersensitivity to patiromer sorbitex calcium or any of its excipients listed in section 6.1.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Reversible causes of hyperkalaemia should be excluded and therapy initiated only if the serum potassium remains elevated and uncontrolled with dietary modification.

Treatment needs to be closely supervised or monitored.

There have been no clinical studies related to the use of Veltassa for duration of greater than 1 year. There have been no clinical studies that have examined the impact of Veltassa on patient mortality.

Veltassa should not replace emergency treatment of hyperkalaemia

The onset of action of Veltassa occurs 4-7 hours after administration. Veltassa could be used in conjunction with other measures to stabilise the myocardium but is not recommended as the sole treatment of patients with hyperkalaemia and ECG changes.

Monitoring

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.

Serum magnesium should be monitored for at least 1 month after initiation of patiromer treatment (see also "**Low Magnesium**").

Serum calcium should be monitored in patients at risk of hypercalcaemia (see also "**Information about calcium**").

Low Magnesium

In clinical studies, serum magnesium values < 1.4 mg/dL (0.58 mmol/L) occurred in 9% of patients treated with patiromer sorbitex calcium, with no patient developing a serum magnesium level < 1.0 mg/dL (0.4 mmol/L). Mean decreases in serum magnesium occurred early during patiromer sorbitex calcium use and were 0.17 mg/dL (0.070 mmol/L) or less throughout treatment. Monitor serum magnesium for at least 1 month after initiation of patiromer sorbitex calcium treatment; continue monitoring if serum magnesium levels decrease. Consider magnesium supplementation in patients who develop low serum magnesium levels on patiromer sorbitex calcium.

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 Pharmacological properties). The benefits and risks of administering this medicinal product should be carefully evaluated in patients at risk of hypercalcaemia. Monitoring serum calcium is recommended in patients at risk for hypercalcemia.

Gastrointestinal Disorders

Patients with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders, or swallowing disorders were not included in the clinical studies. Gastrointestinal ischaemia, necrosis and/or intestinal perforation have been reported with other potassium binders. Patients should be monitored carefully such that the benefits and risks of administering Veltassa can be evaluated before and during treatment.

Discontinuing Veltassa

Veltassa binds potassium. On cessation of this medication, potassium levels will return to pre-treatment levels, reflecting the combined effect of the patient's other treatments (e.g. RAAS inhibitors), dietary intake and medical conditions (e.g. CKD). Patients should be instructed not

to discontinue therapy without consulting their physicians. In clinical studies, serum potassium increased as early as 2 days after the last patiromer sorbitex calcium dose.

Use in renal impairment

There is no data on the administration of Veltassa to patients on peritoneal dialysis. Veltassa reduced serum potassium in the 6 patients on haemodialysis included in the drug development program. There is no data on the use with phosphate binders.

Use in the elderly

Of the total number of subjects exposed to Veltassa in clinical studies, 398 (59.8%) were aged 65 and over, while 132 (19.8%) were aged 75 and over. No special dose and administration guidelines were applied to seniors in these studies.

Paediatric use

There is no data on the safety and efficacy of Veltassa in children aged under 18 years.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Effect of patiromer on other medicinal products

Patiromer sorbitex calcium has the potential to bind some oral co-administered drugs, which could decrease their gastrointestinal absorption and result in a loss of efficacy when taken close to the time Veltassa is administered. As patiromer is not absorbed or metabolised by the body, interactions with other medicinal products outside of the gastrointestinal tract are not expected.

Table 1 and Table 2 show 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 patiromer should be separated by at least 3 hours as a precautionary measure.

Table 1: Recommendations for administration of medicinal products tested for interactions with Veltassa that require separate dosing

Medicinal product	Clinical recommendation	Basis for recommendation
Angiotensin II receptor blockers (ARB)		
telmisartan	separate by at least 3 hours from Veltassa	*in vitro* binding observed
β-adrenoceptor blockers (β-blocker)		
bisoprolol, carvedilol, nebivolol	separate by at least 3 hours from Veltassa	*in vitro* binding observed
Antibiotics		

ciprofloxacin	separate by at least 3 hours from Veltassa	*in vivo* interactions observed but not when separated by 3 hours
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
Blood Glucose Lowering Drugs		
metformin	separate by at least 3 hours from Veltassa	*in vivo* interactions observed but not when separated by 3 hours
Immunosuppressants		
mycophenolate mofetil	separate by at least 3 hours from Veltassa	*in vitro* binding observed
Others		
quinidine	separate by at least 3 hours from Veltassa	*in vitro* binding observed
thiamine		

Table 2: Recommendations for administration of medicinal products tested for interactions with Veltassa that do not require separate dosing

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)		
azilsartan, candesartan, irbesartan, losartan, olmesartan, valsartan	no separation from Veltassa required	*in vitro*: no interaction observed
β-adrenoceptor blockers (β-blocker)		
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		
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		
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		
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		
tacrolimus	no separation from Veltassa required	*in vitro*: no interaction observed
Others		
lithium	no separation from Veltassa required	*in vivo*: no interaction observed
allopurinol, atorvastatin, digoxin, phenytoin, riboflavin, sevelamer		*in vitro*: no interaction observed

Physicians should consider monitoring medicines with a narrow therapeutic index when starting Veltassa.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

There are no data on the effect of Veltassa on fertility in humans.

Male and female fertility were unaffected in rats at oral doses of patiromer up to 5 g/kg/day, 10 times higher than the maximum recommended human dose on a g/kg basis (assuming 50 kg patient body weight).

Use in Pregnancy – (Category B1)

There are no data from the use of Veltassa in pregnant women. Veltassa is not absorbed systemically following oral administration and maternal use is not expected to result in fetal risk.

No adverse effects on embryofetal development were observed in rats and rabbits receiving oral doses of patiromer of up to 6 and 3 g/kg/day, respectively (12 and 6 times, respectively, the maximum recommended human dose on a g/kg basis).

Use in lactation

There are no data from the use of Veltassa in breastfeeding women. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to patiromer is negligible.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

The current safety profile of Veltassa is based on a total of 666 patients from clinical trials, 547 patients with hyperkalaemia from treatment studies and 119 patients at risk of hyperkalaemia from prevention studies.

The majority of the adverse drug reactions reported from trials were gastrointestinal disorders, with the most frequently reported adverse events being constipation, diarrhoea, abdominal pain, flatulence, nausea, vomiting, and hypomagnesaemia (see Table 3). Gastrointestinal disorder events were generally mild to moderate in nature, did not appear to be dose related, generally resolved spontaneously or with treatment, and none were reported as serious.

Table 3: Tabulated list of adverse drug reactions

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

Laboratory Abnormalities

Approximately 4.7% of patients in clinical trials developed hypokalaemia with a serum potassium value < 3.5mEq/L.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

Doses of Veltassa in excess of 50.4 g patiromer per day have not been tested. Since excessive doses of Veltassa may result in hypokalaemia, serum potassium levels should be monitored. If it is determined that medical intervention is required, appropriate measures to restore serum potassium may be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

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

Veltassa increases faecal potassium excretion through binding of potassium in the lumen of the gastrointestinal tract. Binding of potassium reduces the concentration of free potassium in the gastrointestinal lumen, resulting in a reduction of serum potassium levels.

Pharmacodynamic Effects

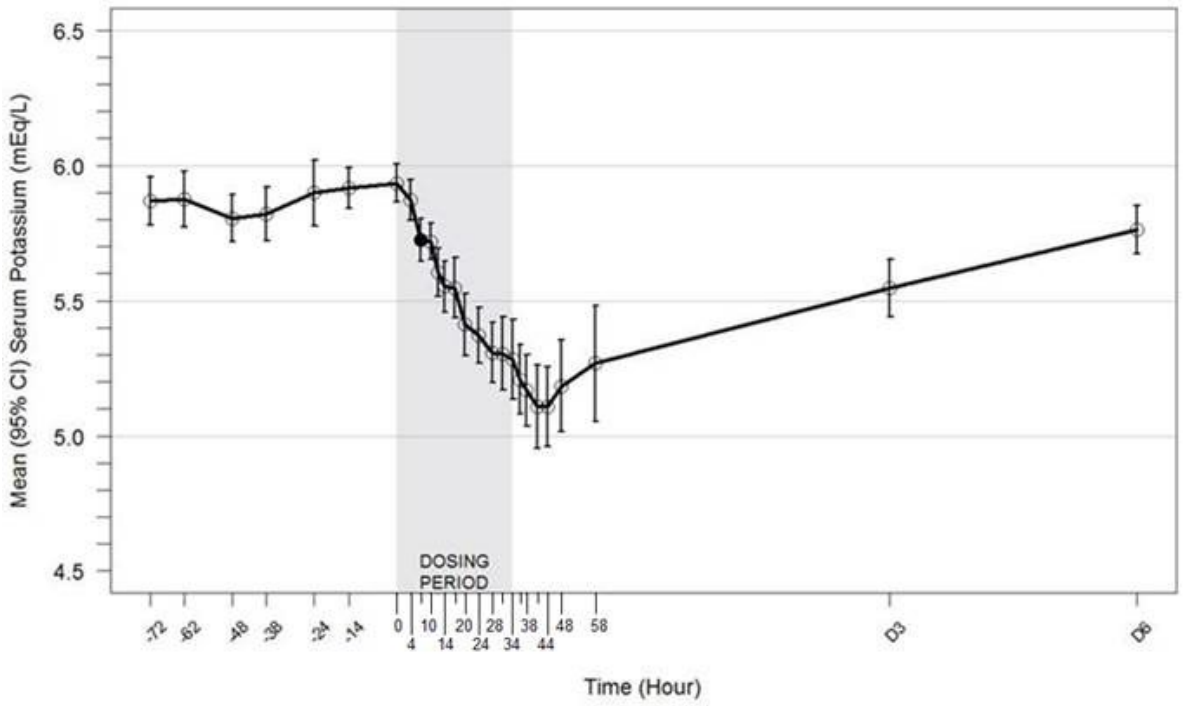
Patiromer has been shown to bind potassium *in vitro* and *in vivo* in experimental animal models.

In a Phase 1 study in healthy adult subjects (6 to 8 subjects per group), patiromer (2.52 g to 50.4 g per day) administered three times a day for 8 days caused a dose-dependent increase in faecal potassium excretion compared with placebo. A corresponding dose-dependent decrease in urinary potassium excretion with no change in serum potassium was also observed. Compared to placebo, patiromer doses of 25.2 and 50.4 g per day significantly decreased mean daily urinary potassium excretion. Daily urinary calcium excretion increased from baseline by 73 mg/day at the 25.2 g dose of patiromer.

In a Phase 1, open-label, multiple-dose crossover study in 12 healthy subjects, 25.2 g of patiromer per day was administered orally as a once daily, twice daily or thrice daily regimen for 6 days in a randomly assigned order. A significant increase in mean daily faecal potassium excretion and concomitant decrease in mean daily urinary potassium excretion were observed during the treatment periods for all three dosing regimens. The mean increase in faecal potassium excretion ranged from 1283 to 1550 mg/day, and the mean decrease in urinary potassium excretion ranged from 1438 to 1534 mg/day across the three dosing regimens. No significant differences were observed among the dosing regimens with respect to mean daily faecal potassium and urinary potassium excretion. This was true for the overall comparison among the three dosing regimens, as well as for the pairwise comparisons. Daily urinary calcium excretion increased from baseline by 53 mg/day, 66 mg/day and 73 mg/day for once daily, twice daily and thrice daily regimens, respectively.

In an open-label, uncontrolled study, 25 patients with hyperkalaemia (mean baseline serum potassium of 5.9 mEq/L) and chronic kidney disease were given a controlled potassium diet for 3 days, followed by 16.8 g patiromer daily (as two divided doses) for 2 days while the controlled diet was continued. A statistically significant reduction in serum potassium (-0.2 mEq/L) was observed at 7 hours after the first dose. Serum potassium levels continued to decline during the 48-hour treatment period (-0.8 mEq/L at 48 hours after the first dose). Potassium levels remained stable for 24 hours after the last dose, then rose during the 4-day observation period following discontinuation of patiromer sorbitex calcium (see Figure 1).

Figure 1: Onset of Action – Mean (95% CI) Serum Potassium (mEq/L) Over Time



* Filled circle indicates the hour when the first statistically significant reduction was identified. A mean reduction of 0.8 mEq/L was observed at 48 hours ($p < 0.001$).
Notes: Hours -72 to 0 = Potassium controlled diet Run-in Period; Hours 0 to 58 = Inpatient Treatment Period with Veltassa 16.8 g daily as divided doses; Hour 58 to Day 6 = Outpatient Follow-Up Period

Clinical trials

The safety and efficacy of Veltassa were demonstrated in a two-part, single-blind randomised withdrawal study that evaluated Veltassa in hyperkalaemic patients with CKD on stable doses of at least one RAAS inhibitor (i.e., angiotensin-converting enzyme inhibitor [ACEI], angiotensin II receptor blocker [ARB], or aldosterone antagonist [AA]).

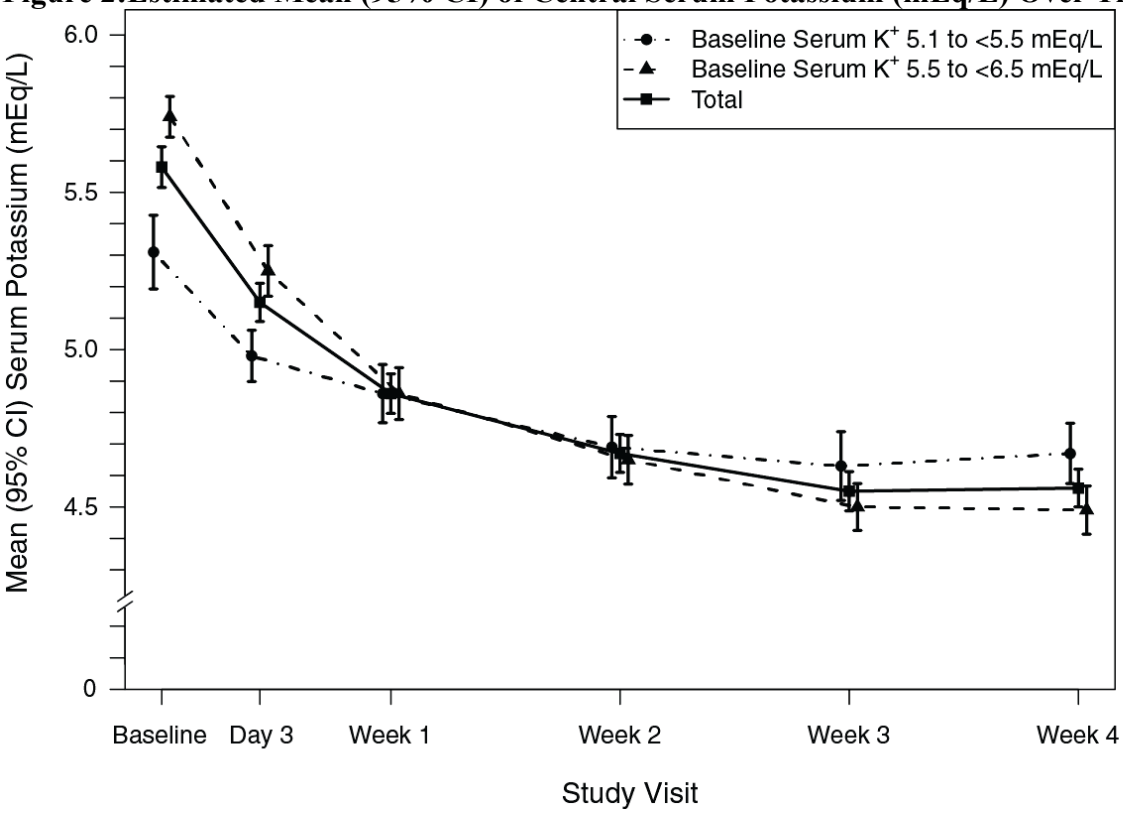
In Part A, 243 patients were treated with Veltassa for 4 weeks. Patients with a baseline serum potassium of 5.1 mEq/L to < 5.5 mEq/L received a starting Veltassa dose of 8.4 g patiromer per day (as a divided dose) and patients with a baseline serum potassium of 5.5 mEq/L to < 6.5 mEq/L received a starting Veltassa dose of 16.8 g per day (as a divided dose). The dose of Veltassa was titrated, as needed, based on the serum potassium level, assessed starting on Day 3 and then at weekly visits (Weeks 1, 2 and 3) to the end of the 4-week treatment period, with the aim of maintaining serum potassium in the target range (3.8 mEq/L to < 5.1 mEq/L). The mean daily doses of Veltassa were 13 g and 21 g in patients with serum potassium of 5.1 to < 5.5 mEq/L and 5.5 to < 6.5 mEq/L, respectively.

The mean age of patients was 64 years, 58% of patients were men, and 98% were Caucasian. Approximately 97% of patients had hypertension, 57% had type 2 diabetes, and 42% had heart failure.

Mean serum potassium levels were 5.58 mEq/L at baseline and the mean (SE) change in serum potassium from Part A Baseline to Part A Week 4 was -1.01 (0.031) mEq/L (see Figure 2); this mean reduction in serum potassium was statistically significant ($p < 0.001$). For the Part A

secondary outcome, 76% (95% CI: 70%, 81%) of patients had a serum potassium in the target range of 3.8 mEq/L to < 5.1 mEq/L at Part A Week 4.

Figure 2:Estimated Mean (95% CI) of Central Serum Potassium (mEq/L) Over Time



In Part B, 107 patients with a Part A baseline serum potassium of 5.5 mEq/L to < 6.5 mEq/L and whose serum potassium was in the target range (3.8 mEq/L to < 5.1 mEq/L) at Part A Week 4 and still receiving RAAS inhibitor medication were randomised to continue Veltassa or to receive placebo for 8 weeks to evaluate the effect of withdrawing Veltassa on serum potassium. In patients randomised to Veltassa, the mean daily dose was 21 g at the start of Part B and during Part B.

The Part B primary endpoint was the change in serum potassium from Part B baseline to the earliest visit at which the patient's serum potassium was first outside of the range of 3.8 to < 5.5 mEq/L or to Part B Week 4 if the patient's serum potassium remained in the range. In Part B, serum potassium rose by 0.72 mEq/L in patients on placebo relative to no change in patients who remained on Veltassa ($p < 0.001$).

More placebo patients (91% [95% CI: 83%, 99%]) developed a serum potassium ≥ 5.1 mEq/L at any time during Part B than Veltassa patients (43% [95% CI: 30%, 56%]), $p < 0.001$. More placebo patients (60% [95% CI: 47%, 74%]) developed a serum potassium ≥ 5.5 mEq/L at any time during Part B than Veltassa patients (15% [95% CI: 6%, 24%]), $p < 0.001$.

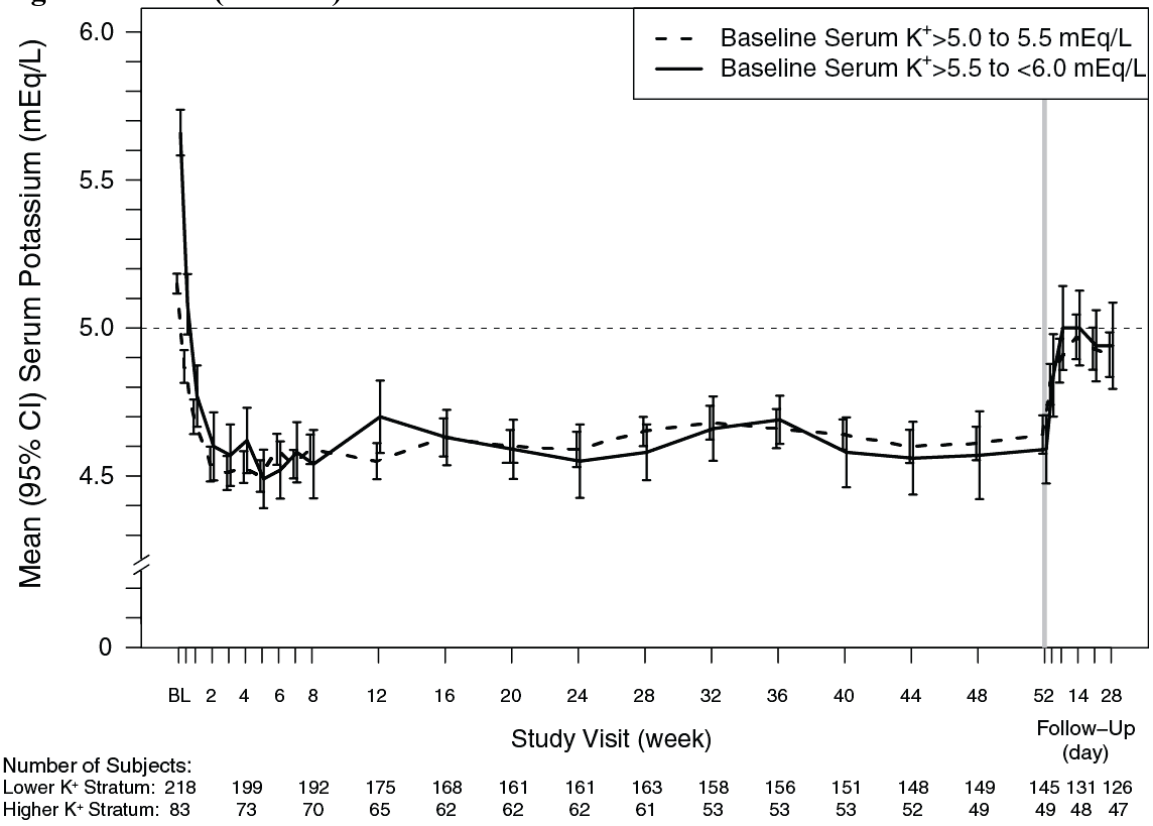
Fifty-two percent (52%) of subjects receiving placebo discontinued RAAS inhibitor medication because of recurrent hyperkalaemia compared with 5% of subjects treated with Veltassa.

The effect of treatment with Veltassa for up to 52 weeks was evaluated in an open-label study of 304 hyperkalaemic patients with CKD and type 2 diabetes mellitus on stable doses of a

RAAS inhibitor. Decreases in serum potassium with Veltassa treatment were maintained over 1 year of chronic treatment with a low incidence of hypokalaemia and the majority of subjects reaching and maintaining target serum potassium levels. In patients with a baseline serum potassium of > 5.0 to 5.5 mEq/L who received an initial dose of 8.4 g Veltassa per day (as a divided dose), the mean daily dose was 14 g; in those with a baseline serum potassium of > 5.5 to < 6.0 mEq/L who received an initial dose of 16.8 g Veltassa per day (as a divided dose), the mean daily dose was 20 g during the entire study (see Figure 3).

After stopping Veltassa, significant increases in least squares mean serum potassium levels were seen by day 3 post-treatment. Patients remained on all RAAS inhibitors for 28 days after discontinuation of Veltassa treatment, during which time the increase in serum potassium remained statistically significant.

Figure 3:Mean (95% CI) Serum Potassium Over Time



Effect of Food

In an open-label study (RLY5016-401 – TOURMALINE), 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.

5.2 PHARMACOKINETIC PROPERTIES

Veltassa works by binding potassium in the gastrointestinal tract and thus the serum drug concentration is not relevant for its efficacy. Due to the insolubility and non-absorptive characteristics of Veltassa, many classical pharmacokinetic studies cannot be carried out.

5.3 PRECLINICAL SAFETY DATA

In radiolabelled ADME studies in rats and dogs, patiromer was not systemically absorbed and was excreted in the faeces. 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.

Genotoxicity

Patiromer was not genotoxic in the bacterial reverse mutation test (Ames assay), *in vitro* chromosomal aberration assay (Chinese Hamster Ovary cells) or rat micronucleus test.

Carcinogenicity

Carcinogenicity studies with Veltassa have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Each sachet also contains Xanthan gum.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

Please see Section 4.5 Interactions with other medicines and other forms of interactions.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store at 2 to 8°C. (Refrigerate. Do not freeze.)

Veltassa may be stored below 25°C for up to 6 months.

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

Protect from heat.

6.5 NATURE AND CONTENTS OF CONTAINER

Veltassa powder for oral suspension is available in Al laminated with PE/paper sachets.
Pack Size: Carton boxes containing 30 sachets.

Not all strengths may be marketed.

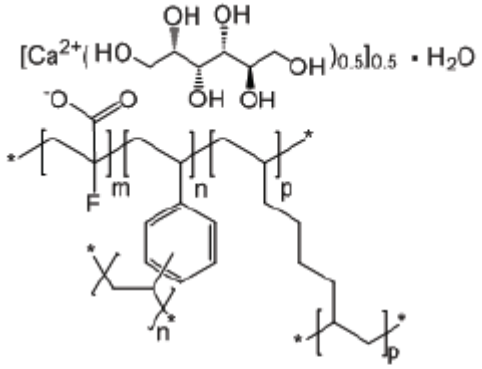
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Patiromer sorbitex calcium is a crosslinked polymer of calcium, hydrolyzed divinylbenzene-Me 2-fluoro-2-propenoate-1,7-octadiene polymer sorbitol complexes. The molecular weight of a 100 micrometre patiromer sorbitex calcium bead, calculated using an experimentally derived value for density and the theoretical calculated value for volume, is estimated to be 5.6×10^{17} g/mol.

Chemical structure



m = number of 2-fluoro-2-propenoate groups m = 0.91

n, p = number of crosslinking groups n + p = 0.09

' H_2O = associated water

* = indicates an extended polymeric network

Empirical formula: $C_{613}H_{765}F_{114}O_{399}Ca_{57}$

CAS number

1415477-49-4

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 – Prescription Only Medicine

8 SPONSOR

Seqirus Pty Ltd
63 Poplar Rd,
Parkville VIC 3052
Australia
1800 642 865 (Within Australia).

9 DATE OF FIRST APPROVAL

12 December 2017

10 DATE OF REVISION

18 March 2024

Summary table of changes

Section changed	Summary of new information
8	Sponsor details updated