VELTASSA- patiromer powder, for suspension
Relypsa, Inc.
Reference Label Set Id: d1e6f3cc-3436-475d-9667-6722ed49ba61

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VELTASSA® safely and effectively. See full prescribing information for VELTASSA.

VELTASSA (patiromer) for oral suspension
Initial U.S. Approval: 2015

INDICATIONS AND USAGE

Veltassa is a potassium binder indicated for the treatment of hyperkalemia. (1)

Limitation of Use

Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action. (1)

DOSAGE AND ADMINISTRATION

- The recommended starting dose of Veltassa is 8.4 grams administered orally once daily. (2.2)
- Adjust dose by 8.4 grams daily as needed at one-week intervals to obtain desired serum potassium target range. (2.2)

DOSAGE FORMS AND STRENGTHS

- Powder: 8.4 grams, 16.8 grams and 25.2 grams patiromer packets. (3)

CONTRAINDICATIONS

- Known hypersensitivity to Veltassa or any of its components. (4)

WARNINGS AND PRECAUTIONS

- Worsening of Gastrointestinal Motility. (5.1)
- Hypomagnesemia. (5.2)

ADVERSE REACTIONS

- Most common adverse reactions (incidence ≥ 2%) are constipation, hypomagnesemia, diarrhea, nausea, abdominal discomfort and flatulence. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Relypsa at 1-844-VELTASSA (1-844-835-8277) or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

DRUG INTERACTIONS

- Take other orally administered drugs at least 3 hours before or 3 hours after Veltassa. (2.1, 7)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 5/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Veltassa is indicated for the treatment of hyperkalemia.

Limitation of Use: Veltassa should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action *[see Clinical Pharmacology (12.2)]*.

2 DOSAGE AND ADMINISTRATION

2.1 General Information

Administer Veltassa at least 3 hours before or 3 hours after other oral medications *[see Drug Interactions (7) and Clinical Pharmacology (12.3)]*.

Do not heat Veltassa (e.g., microwave) or add to heated foods or liquids. Do not take Veltassa in its dry form.

2.2 Recommended Dosing and Titration

The recommended starting dose of Veltassa is 8.4 grams patiromer once daily. Monitor serum potassium and adjust the dose of Veltassa based on the serum potassium level and the desired target range. The dose may be increased or decreased, as necessary, to reach the desired serum potassium concentration, up to a maximum dose of 25.2 grams once daily. The dose can be up-titrated based on

serum potassium level at 1-week or longer intervals, in increments of 8.4 grams.

2.3 Preparation of Veltassa

Prepare each dose immediately prior to administration.

Measure 1/3 cup 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.

3 DOSAGE FORMS AND STRENGTHS

Veltassa is an off-white to light-brown powder for oral suspension packaged in single-use packets containing 8.4 grams, 16.8 grams or 25.2 grams patiromer.

4 CONTRAINDICATIONS

Veltassa is contraindicated in patients with a history of a hypersensitivity reaction to Veltassa or any of its components *[see Adverse Reactions (6.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Worsening of Gastrointestinal Motility

Avoid use of Veltassa in patients with severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders, because Veltassa may be ineffective and may worsen gastrointestinal conditions.

Patients with a history of bowel obstruction or major gastrointestinal surgery, severe gastrointestinal disorders, or swallowing disorders were not included in the clinical studies.

5.2 Hypomagnesemia

Veltassa binds to magnesium in the colon, which can lead to hypomagnesemia. In clinical studies, hypomagnesemia was reported as an adverse reaction in 5.3% of patients treated with Veltassa *[see Adverse Reactions (6.1)]*. Monitor serum magnesium. Consider magnesium supplementation in patients who develop low serum magnesium levels on Veltassa.

6 ADVERSE REACTIONS

The following adverse reaction is discussed in greater detail elsewhere in the label:

- Hypomagnesemia *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of Veltassa cannot be directly compared to rates in the clinical trials of other drugs and may not reflect the rates observed in practice.

In the safety and efficacy clinical trials, 666 adult patients received at least one dose of Veltassa, including 219 exposed for at least 6 months and 149 exposed for at least one year.

Table 1 provides a summary of the most common adverse reactions (occurring in ≥ 2% of patients) in patients treated with Veltassa in these clinical trials. Most adverse reactions were mild to moderate. Constipation generally resolved during the course of treatment.

Table 1: Adverse Reactions Reported in ≥ 2% of Patients

Adverse Reactions	Patients treated with Veltassa (N=666)
Constipation	7.2%
Hypomagnesemia	5.3%
Diarrhea	4.8%
Nausea	2.3%
Abdominal discomfort	2.0%
Flatulence	2.0%

During the clinical studies, the most commonly reported adverse reactions leading to discontinuation of Veltassa were gastrointestinal adverse reactions (2.7%), including vomiting (0.8%), diarrhea (0.6%), constipation (0.5%) and flatulence (0.5%).

Mild to moderate hypersensitivity reactions were reported in 0.3% of patients treated with Veltassa in clinical trials. Reactions have included edema of the lips.

Laboratory Abnormalities

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

Approximately 9% of patients in clinical trials developed hypomagnesemia with a serum magnesium value < 1.4 mg/dL.

7 DRUG INTERACTIONS

In clinical studies, Veltassa decreased systemic exposure of some coadministered oral medications *[see Clinical Pharmacology (12.3)]*. Binding of Veltassa to other oral medications could cause decreased gastrointestinal absorption and loss of efficacy when taken close to the time Veltassa is administered. Administer other oral medications at least 3 hours before or 3 hours after Veltassa *[see Dosage and Administration (2.1) and Clinical Pharmacology (12.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Veltassa is not absorbed systemically following oral administration and maternal use is not expected to result in fetal risk.

8.2 Lactation

Risk Summary

Veltassa is not absorbed systemically by the mother, so breastfeeding is not expected to result in risk to the infant.

8.4 Pediatric Use

Safety and efficacy in pediatric patients have not been established.

8.5 Geriatric Use

Of the 666 patients treated with Veltassa in clinical studies, 59.8% were age 65 and over, and 19.8%

were age 75 and over. No overall differences in effectiveness were observed between these patients and younger patients. Patients age 65 and older reported more gastrointestinal adverse reactions than younger patients.

8.6 Renal Impairment

Of the 666 patients treated with Veltassa in clinical studies, 93% had chronic kidney disease (CKD). No special dosing adjustments are needed for patients with renal impairment.

10 OVERDOSAGE

Doses of Veltassa in excess of 50.4 grams per day have not been tested. Excessive doses of Veltassa may result in hypokalemia. Restore serum potassium if hypokalemia occurs.

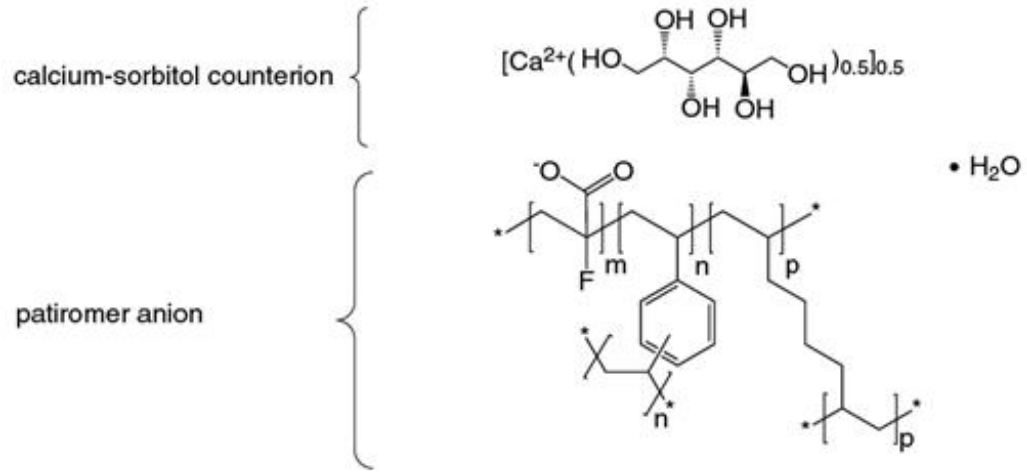
11 DESCRIPTION

Veltassa is a powder for suspension in water for oral administration. The active ingredient is patiromer sorbitex calcium which consists of the active moiety, patiromer, a non-absorbed potassium-binding polymer, and a calcium-sorbitol counterion. Each gram of patiromer is equivalent to a nominal amount of 2 grams of patiromer sorbitex calcium.

The chemical name for patiromer sorbitex calcium is cross-linked polymer of calcium 2-fluoroprop-2-enoate with diethenylbenzene and octa-1,7-diene, combination with D-glucitol.

Patiromer sorbitex calcium is an amorphous, free-flowing powder that is composed of individual spherical beads. Patiromer sorbitex calcium is insoluble in solvents such as water, 0.1 M HCl, n-heptane and methanol. The chemical structure of patiromer sorbitex calcium is presented in Figure 1.

Figure 1: Chemical Structure of Patiromer Sorbitex Calcium



Each packet of Veltassa contains 8.4 grams, 16.8 grams or 25.2 grams of patiromer, the active moiety. The inactive ingredient is xanthan gum.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Veltassa is a non-absorbed, cation exchange polymer that contains a calcium-sorbitol counterion.

Veltassa increases fecal 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.

12.2 Pharmacodynamics

In a Phase 1 study in healthy adult subjects (6 to 8 subjects per group), Veltassa (0 grams to 50.4 grams per day) administered three times a day for 8 days caused a dose-dependent increase in fecal potassium excretion. A corresponding dose-dependent decrease in urinary potassium excretion with no change in serum potassium were also observed. Compared to placebo, Veltassa doses of 25.2 and 50.4 grams per day significantly decreased mean daily urinary potassium excretion.

In a Phase 1, open-label, multiple-dose crossover study in 12 healthy subjects, 25.2 grams 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 fecal 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 fecal 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 fecal potassium and urinary potassium excretion. This was true for the overall comparison among the three dosing regimens, as well as for the pairwise comparisons.

In an open-label, uncontrolled study, 25 patients with hyperkalemia (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 grams patiromer daily (as 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 Veltassa.

12.3 Pharmacokinetics

Absorption

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

Effect of Food

Veltassa can be taken with or without food. In an open-label study, 114 patients with hyperkalemia were randomized to Veltassa 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 Veltassa were similar between groups.

Drug Interactions

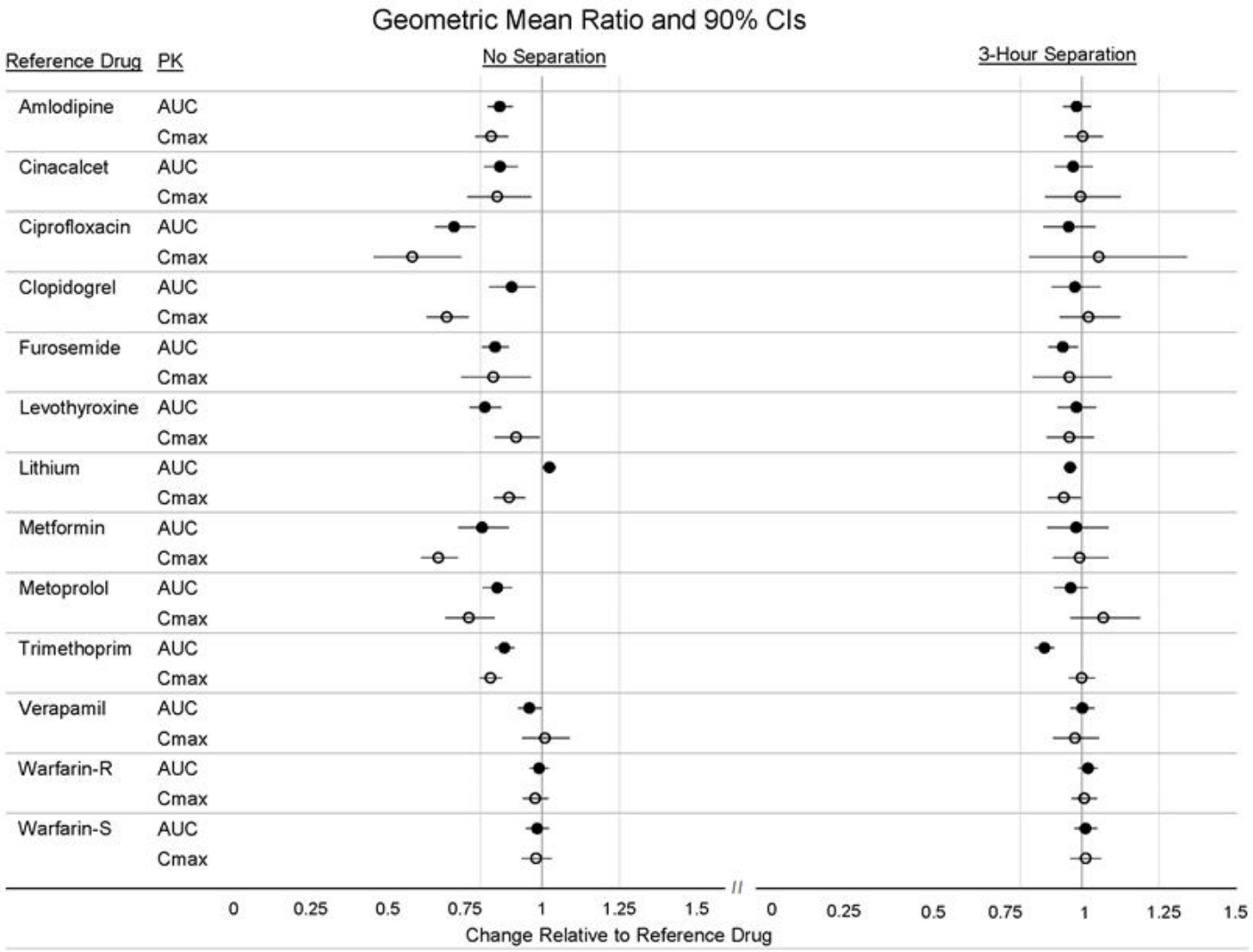
Twenty-eight (28) drugs were tested to determine the potential for interaction with Veltassa.

Fourteen (14) drugs tested did not show an *in vitro* interaction with Veltassa (acetylsalicylic acid, allopurinol, amoxicillin, apixaban, atorvastatin, cephalexin, digoxin, glipizide, lisinopril, phenytoin, riboflavin, rivaroxaban, spironolactone and valsartan).

Twelve (12) of the 14 drugs that showed an *in vitro* interaction were subsequently tested *in vivo*. These studies in healthy volunteers showed that Veltassa did not alter the systemic exposure of amlodipine,

cinacalcet, clopidogrel, furosemide, lithium, metoprolol, trimethoprim, verapamil or warfarin when coadministered with Veltassa. Veltassa decreased the systemic exposure of coadministered ciprofloxacin, levothyroxine and metformin. However, there was no interaction when Veltassa and these drugs were taken 3 hours apart (Figure 2) *[see Drug Interactions (7)]*.

Figure 2: Effects of Veltassa on the Pharmacokinetic Exposures of Other Orally Administered Medications with No Dosing Separation and with a 3-Hour Separation



13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Patiromer was not genotoxic in the reverse mutation test (Ames assay), chromosome aberration or rat micronucleus assays.

Carcinogenicity studies have not been performed.

Patiromer did not impair the fertility in male or female rats at doses up to 10-fold the maximum recommended human dose (MRHD).

14 CLINICAL STUDIES

14.1 Two-Part, Randomized Withdrawal Study

The efficacy of Veltassa was demonstrated in a two-part, single-blind randomized withdrawal study that evaluated Veltassa in hyperkalemic patients with CKD on stable doses of at least one renin-angiotensin-aldosterone system inhibitor (i.e., angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, or aldosterone antagonist).

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 grams 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 grams patiromer 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).

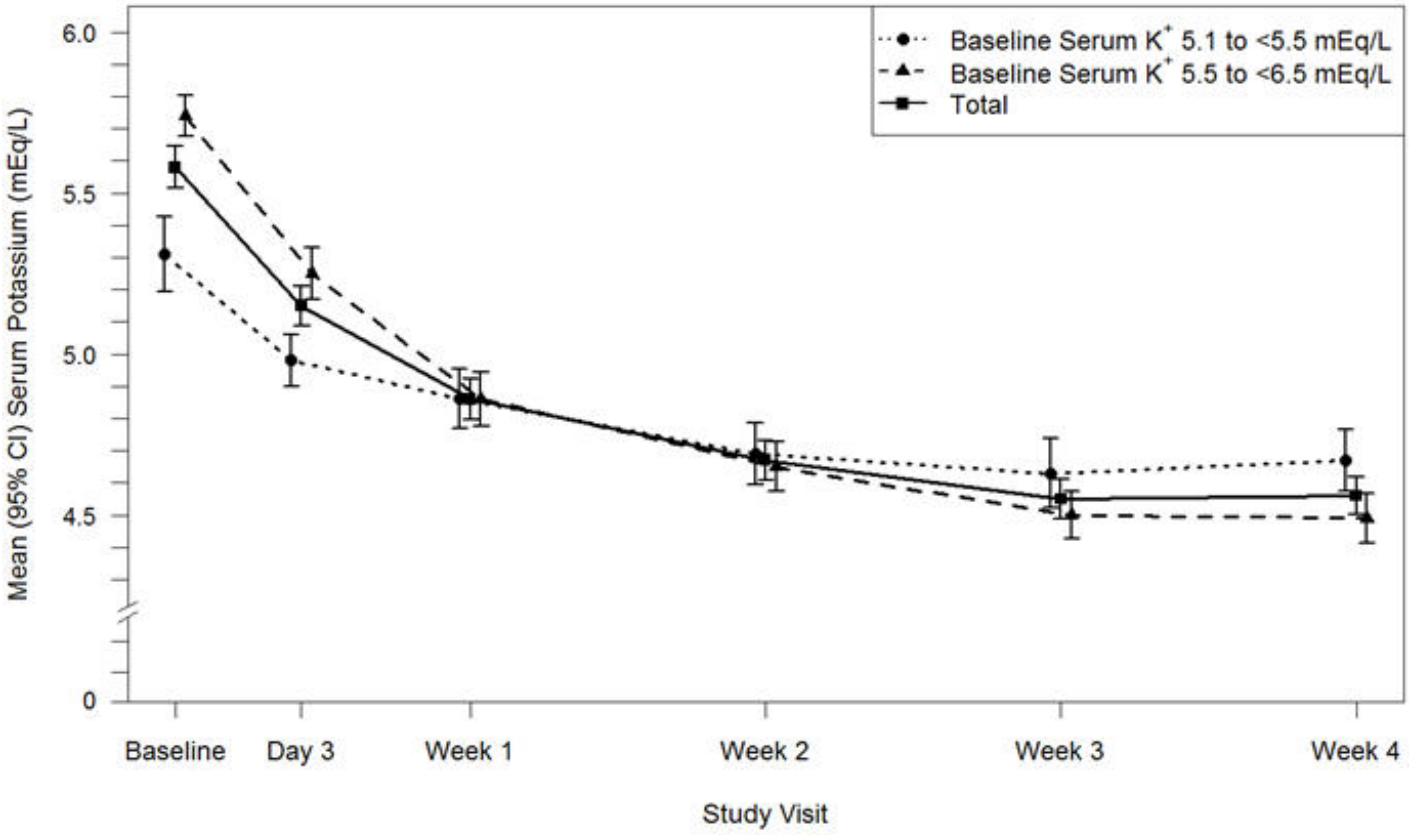
The mean age of patients was 64 years, 58% of patients were men, and 98% were Caucasian. Approximately 97% of patients had hypertension, 57% had type 2 diabetes, and 42% had heart failure.

Results for the Part A primary endpoint, the change in serum potassium from Baseline to Week 4, are summarized in Table 2. Mean serum potassium over time for the intent-to-treat population is displayed in Figure 3. For the Part A secondary endpoint, 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 Week 4. The mean daily doses of Veltassa were 13 grams and 21 grams in patients with serum potassium of 5.1 to < 5.5 mEq/L and 5.5 to < 6.5 mEq/L, respectively.

Table 2: Veltassa Treatment Phase (Part A): Primary Endpoint

	Baseline Potassium		**Overall Population (n=237)**
	5.1 to < 5.5 mEq/L (n=90)	**5.5 to < 6.5 mEq/L (n=147)**	
	Serum Potassium (mEq/L)		
Baseline, mean (SD)	5.31 (0.57)	5.74 (0.40)	5.58 (0.51)
Week 4 Change from Baseline, Mean ± SE (95% CI)	-0.65 ± 0.05 (-0.74, -0.55)	-1.23 ± 0.04 (-1.31, -1.16)	-1.01 ± 0.03 (-1.07, -0.95)
***p*-value**			< 0.001

Figure 3: 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 randomized to continue Veltassa or to receive placebo to evaluate the effect of withdrawing Veltassa on serum potassium. In patients randomized to Veltassa, the mean daily dose was 21 grams 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 who were switched to placebo, versus no change in patients who remained on Veltassa. Results are summarized in Table 3.

Table 3: Randomized, Placebo-Controlled Withdrawal Phase (Part B): Primary Endpoint

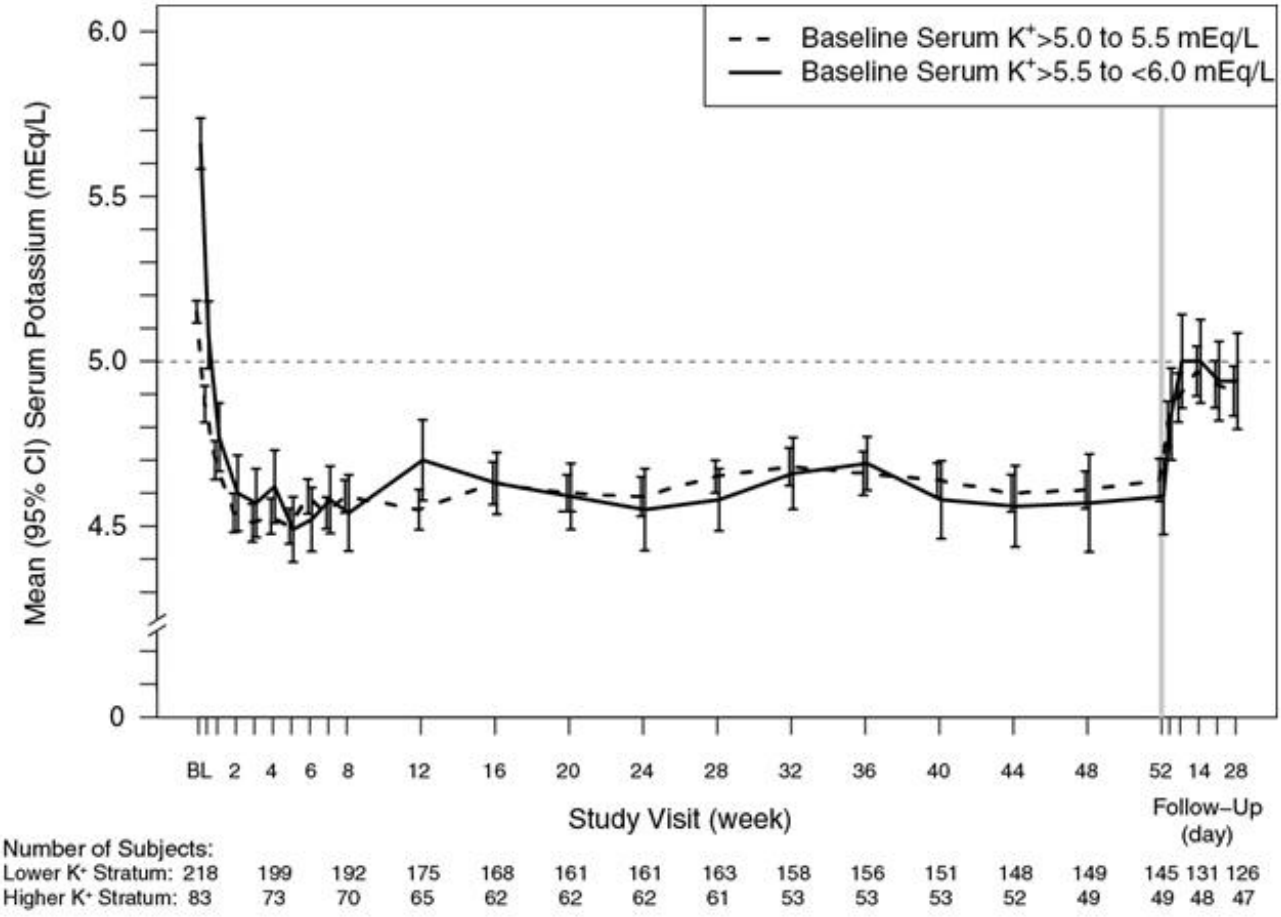
	Placebo (n=52)	**Veltassa (n=55)**	**Difference**	
			Estimate (95% CI)	***p*-value**
Estimated Median Change in Serum Potassium from Baseline (mEq/L)	0.72	0.00	0.72 (0.46, 0.99)	< 0.001

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%), $p < 0.001$.

14.2 One-Year Study

The effect of treatment with Veltassa for up to 52 weeks was evaluated in an open-label study of 304 hyperkalemic patients with CKD and type 2 diabetes mellitus on RAAS inhibitor therapy. Figure 4 shows that the treatment effect on serum potassium was maintained during continued therapy. In patients with a baseline serum potassium of > 5.0 to 5.5 mEq/L who received an initial dose of 8.4 grams patiromer per day (as a divided dose), the mean daily dose was 14 grams; in those with a baseline serum potassium of > 5.5 to < 6.0 mEq/L who received an initial dose of 16.8 grams patiromer per day (as a divided dose), the mean daily dose was 20 grams during the entire study.

Figure 4: Mean (95% CI) Serum Potassium over Time



16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Veltassa is supplied as a powder for oral suspension formulated with xanthan gum. Veltassa is packaged in single-use packets containing 8.4 grams, 16.8 grams or 25.2 grams patiromer as follows:

Veltassa (grams)	Single Use Packet	Carton of 4 Packets	Carton of 30 Packets
8.4	NDC 53436-084-01	NDC 53436-084-04	NDC 53436-084-30
16.8	NDC 53436-168-01	-	NDC 53436-168-30
25.2	NDC 53436-252-01	-	NDC 53436-252-30

16.2 Stability and Storage

Veltassa should be stored in the refrigerator at 2°C to 8°C (36°F to 46°F).

If stored at room temperature (25°C ± 2°C [77°F ± 4°F]), Veltassa must be used within 3 months of

being taken out of the refrigerator. For either storage condition, do not use Veltassa after the expiration date printed on the packet.

Avoid exposure to excessive heat above 40°C (104°F).

17 PATIENT COUNSELING INFORMATION

Drug Interactions

Advise patients who are taking other oral medication to separate the dosing of Veltassa by at least 3 hours (before or after) *[see Drug Interactions (7)]*.

Dosing Recommendations

Inform patients to take Veltassa as directed and adhere to their prescribed diets.

Inform patients that Veltassa should not be heated (e.g., microwaved) or added to heated foods or liquids and should not be taken in its dry form.

Manufactured for:

Relypsa, Inc.
Redwood City, CA 94063

Version 05; May 2018

PRINCIPAL DISPLAY PANEL - 8.4 g Packet Carton

30 packets
NDC 53436-084-30

Veltassa®
(patiromer)

For Oral Suspension

www.veltassa.com

Each packet contains 8.4 grams of patiromer.
Dispense as 1 box; 30-day supply.

Rx only

8.4 g

GLUE AREA

relypsa

3 53436-084-30 s

LOT XXXX
EXP MM/YYYY
(Serialization Information)

20000XXXX

30 packets
NDC 53436-084-30

Veltassa®
(patiromer)

VELTASSA

For Oral Suspension

www.veltassa.com

Each packet contains 8.4 grams of patiromer.
Dispense as 1 box; 30-day supply.

TOP PANEL

Rx only

8.4 g

Each packet contains 8.4 grams* of patiromer and the inactive ingredient, xanthan gum.

* Equivalent to a nominal amount of 16.8 grams of patiromer sorbitex calcium.

8.4 g

◀Pull to open

Veltassa®
(patiromer)
For Oral Suspension
30 packets
8.4 g
www.veltassa.com

Directions for Use:
Measure 1/3 cup of water. Pour half of the water into a glass. Empty packet contents into the glass. Stir well. Then add the remaining water. Stir well and drink immediately. If powder remains in the glass after drinking, add more water, stir, and then drink immediately. Repeat as needed to ensure the entire dose is administered. Do not heat Veltassa or add to heated foods or liquids. Administer Veltassa at least 3 hours before or 3 hours after other oral medications or as directed by your doctor.

Usual Dosage: See prescribing information.

Keep this and all medications out of the reach of children.

Veltassa should be stored in the refrigerator at 36°F to 46°F (2°C to 8°C). If stored at room temperature [77°F ± 4°F (25°C ± 2°C)], Veltassa must be used within 3 months of being taken out of the refrigerator. For either storage condition, do not use after the expiration date printed on the packet.

Avoid excessive heat above 104°F (40°C).

TEXT PANEL

Manufactured for:
Relypsa, Inc.
Redwood City, CA 94063

Product of Canada

BOTTOM PANEL

GLUE

PRINCIPAL DISPLAY PANEL - 16.8 g Packet Carton

30 packets
NDC 53436-168-30

Veltassa®
(patiromer)

For Oral Suspension

www.veltassa.com

Each packet contains 16.8 grams of patiromer.
Dispense as 1 box; 30-day supply.

Rx only

16.8 g

GLUE AREA

relypsa

FPO
LOT XXXX
EXP MM/YYYY
(Serialization information)

2000000XXXX

30 packets
NDC 53436-168-30

VELTASSA

Veltassa®
(patiromer)
For Oral Suspension

www.veltassa.com

Each packet contains 16.8 grams of patiromer.
Dispense as 1 box; 30-day supply.

TOP PANEL

Rx only

16.8 g

Each packet contains 16.8 grams* of patiromer and the inactive ingredient, xanthan gum.

*Equivalent to a nominal amount of 33.6 grams of patiromer sorbitex calcium.

16.8 g

◀Pull to open

Veltassa®
(patiromer)
For Oral Suspension

30 packets

16.8 g

www.veltassa.com

Directions for Use:
Measure 1/3 cup of water. Pour half of the water into a glass. Empty packet contents into the glass. Stir well. Then add the remaining water. Stir well and drink immediately. If powder remains in the glass after drinking, add more water, stir, and then drink immediately. Repeat as needed to ensure the entire dose is administered. Do not heat Veltassa or add to heated foods or liquids. Administer Veltassa at least 3 hours before or 3 hours after other oral medications or as directed by your doctor.

Usual Dosage: See prescribing information.

Keep this and all medications out of the reach of children.

Veltassa should be stored in the refrigerator at 36°F to 46°F (2°C to 8°C). If stored at room temperature [77°F ± 4°F (25°C ± 2°C)], Veltassa must be used within 3 months of being taken out of the refrigerator. For either storage condition, do not use after the expiration date printed on the packet.

Avoid excessive heat above 104°F (40°C).

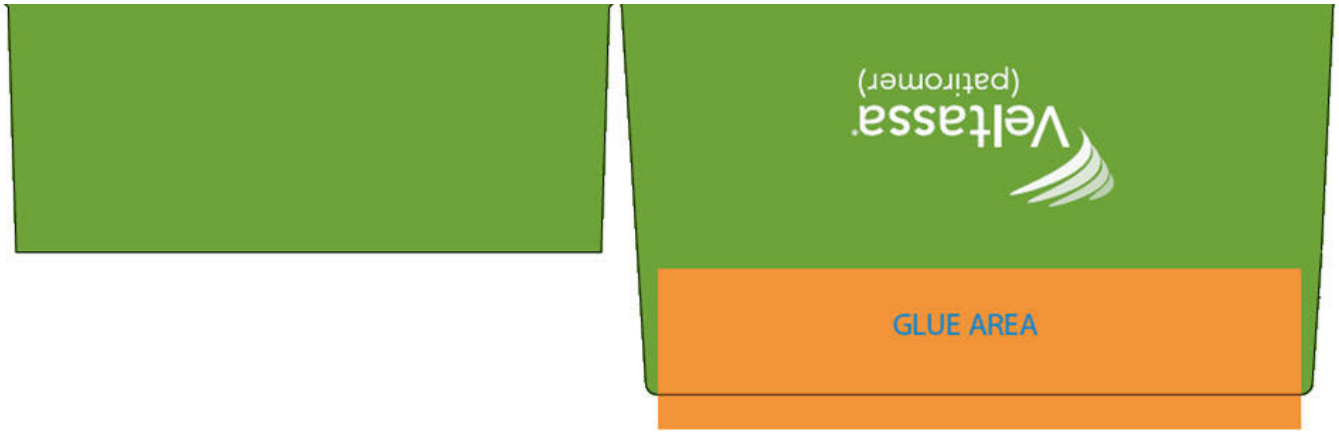
TEXT PANEL

Manufactured for:
Relypsa, Inc.
Redwood City, CA 94063

Product of Canada

BOTTOM PANEL

GLU



PRINCIPAL DISPLAY PANEL - 25.2 g Packet Carton

30 packets
NDC 53436-252-30

Veltassa®
(patiromer)

For Oral Suspension

www.veltassa.com

Each packet contains 25.2 grams of patiromer.
Dispense as 1 box; 30-day supply.

Rx only

25.2 g

GLUE AREA

relypsa

53436-252-30

2000000000

Lot XXXX
Exp MM/YYYY
FPO
(Serialization information)

(Serialization information)

www.veltassa.com

25.2 g

Veltassa®
(patiromer)
For Oral Suspension

30 packets

30 packets
NDC 53436-252-30

VELTASSA

Veltassa®
(patiromer)
For Oral Suspension

www.veltassa.com

Each packet contains 25.2 grams of patiromer.
Dispense as 1 box; 30-day supply.

TOP PANEL

Rx only

25.2 g

Each packet contains 25.2 grams* of patiromer and the inactive ingredient, xanthan gum.

*Equivalent to a nominal amount of 50.4 grams of patiromer sorbitex calcium.

25.2 g

◀Pull to open

Directions for Use:

Measure 1/3 cup of water. Pour half of the water into a glass. Empty packet contents into the glass. Stir well. Then add the remaining water. Stir well and drink immediately. If powder remains in the glass after drinking, add more water, stir, and then drink immediately. Repeat as needed to ensure the entire dose is administered. Do not heat Veltassa or add to heated foods or liquids. Administer Veltassa at least 3 hours before or 3 hours after other oral medications or as directed by your doctor.

Usual Dosage: See prescribing information.

Keep this and all medications out of the reach of children.

Veltassa should be stored in the refrigerator at 36°F to 46°F (2°C to 8°C). If stored at room temperature [77°F ± 4°F (25°C ± 2°C)], Veltassa must be used within 3 months of being taken out of the refrigerator. For either storage condition, do not use after the expiration date printed on the packet.

Avoid excessive heat above 104°F (40°C).

TEXT PANEL

Manufactured for:
Relypsa, Inc.
Redwood City, CA 94063

Product of Canada

30 packets

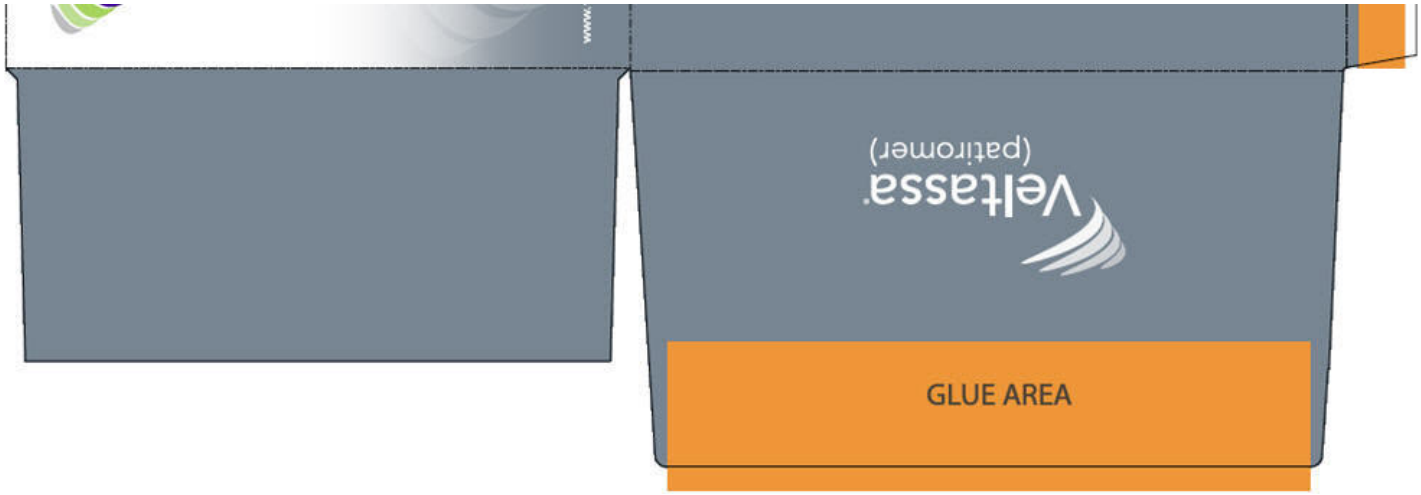
Veltassa®
(patiromer)
For Oral Suspension

25.2 g

www.veltassa.com

BOTTOM PANEL

GLU



VELTASSA

patiromer powder, for suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53436-084
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
patiromer (UNII: 1FQ2RY5YHH) (patiromer - UNII:1FQ2RY5YHH)	patiromer	8.4 g

Inactive Ingredients	
Ingredient Name	**Strength**
xanthan gum (UNII: TTV12P4NEE)	0.12 g

Product Characteristics			
Color	WHITE (off-white to light-brown)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53436-084-04	4 in 1 CARTON	10/23/2015	
1	NDC:53436-084-01	1 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:53436-084-30	30 in 1 CARTON	10/23/2015	
2	NDC:53436-084-01	1 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:53436-084-92	4 in 1 CARTON	05/01/2016	
3	NDC:53436-084-91	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205739	10/23/2015	

VELTASSA

patiromer powder, for suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53436-168
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
patiromer (UNII: 1FQ2RY5YHH) (patiromer - UNII:1FQ2RY5YHH)	patiromer	16.8 g

Inactive Ingredients

Ingredient Name	Strength
xanthan gum (UNII: TTV12P4NEE)	0.24 g

Product Characteristics

Color	WHITE (off-white to light-brown)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53436-168-30	30 in 1 CARTON	10/23/2015	
1	NDC:53436-168-01	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205739	10/23/2015	

VELTASSA

patiromer powder, for suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53436-252
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
patiromer (UNII: 1FQ2RY5YHH) (patiromer - UNII:1FQ2RY5YHH)	patiromer	25.2 g

Inactive Ingredients	
Ingredient Name	**Strength**
xanthan gum (UNII: TTV12P4NEE)	0.36 g

Product Characteristics			
Color	WHITE (off-white to light-brown)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53436-252-30	30 in 1 CARTON	10/23/2015	
1	NDC:53436-252-01	1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205739	10/23/2015	

Labeler - Relypsa, Inc. (808446087)

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