VELTASSA® (patiromer) for Oral Suspension  

**What VELTASSA Treats**
VELTASSA is a potassium binder approved for the treatment of hyperkalemia. VELTASSA should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action. People with this condition have elevated potassium levels in their blood.

*Please see Important Safety Information & Limitations of Use for VELTASSA on the following page. Please visit www.VELTASSA.com for more information, including the full Prescribing Information.*

**About Hyperkalemia**
Hyperkalemia is generally defined as blood potassium levels of >5.0 mEq/L. If not treated, some people with hyperkalemia can be at risk for abnormal heart rhythms and sudden death.

**Mechanism of Action**
Available in powder form consisting of smooth, spherical beads, VELTASSA is mixed with water and taken daily by mouth. VELTASSA is not absorbed and it works within the gastrointestinal (GI) tract. It binds to potassium in exchange for calcium, primarily in the colon. The potassium is then excreted from the body through the normal excretion process.

**Clinical Data**
The FDA approval of VELTASSA was based on a clinical development program that studied patients who are representative of people who typically experience high blood potassium levels, including people who had chronic kidney disease (CKD), heart failure, diabetes and hypertension.

- The pivotal Phase 3 OPAL-HK study showed VELTASSA significantly decreased potassium levels in hyperkalemic CKD patients taking RAAS inhibitors (mean decrease of -1.01 ± 0.03 mEq/L from baseline; p<0.001). At four weeks, 76 percent of patients had potassium levels in the target range (3.8 to <5.1 mEq/L). During the second part of the trial, patients taking VELTASSA had no change in median potassium from baseline (0.00 mEq/L), whereas potassium levels significantly increased in the placebo group (0.72 mEq/L; p<0.001).

- The Phase 2 AMETHYST-DN trial evaluated use of VELTASSA over 52 weeks in hyperkalemic patients with CKD and type 2 diabetes who were taking RAAS inhibitors. Throughout the year-long study, the majority of patients had potassium levels in the target range (3.8-5.0 mEq/L).

- An open-label, uncontrolled, Phase 1 study evaluated VELTASSA’s onset-of-action in 25 hyperkalemic CKD patients. The mean baseline blood potassium level was 5.9 mEq/L. A statistically significant reduction in blood
potassium levels was first observed at 7 hours after the first dose. Potassium levels continued to decline during the 48-hour treatment period of the study (-0.8 mEq/L at 48 hours after the first dose).

✓ In the clinical trials, most adverse reactions were mild to moderate. The most common adverse reactions in all trials included constipation (7.2 percent: 5.4 percent mild and 1.8 percent moderate), hypomagnesemia (low magnesium levels; 5.3 percent), diarrhea (4.8 percent), nausea (2.3 percent), abdominal discomfort (2.0 percent) and flatulence (2.0 percent).

**Indication & Limitation of Use**

VELTASSA is indicated for the treatment of hyperkalemia.

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

**Important Safety Information**

**Contraindications**

VELTASSA is contraindicated in patients with a history of a hypersensitivity reaction to VELTASSA or any of its components.

**Worsening of Gastrointestinal Motility**

Use of VELTASSA should be avoided 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 clinical studies.

**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 percent of patients treated with VELTASSA. Approximately 9 percent of patients in clinical trials developed hypomagnesemia with a serum magnesium value <1.4 mg/dL. Doctors should monitor serum magnesium and consider magnesium supplementation in patients who develop low serum magnesium levels.

**Adverse Reactions**

The most common adverse reactions (incidence ≥ 2 percent) were constipation, hypomagnesemia, diarrhea, nausea, abdominal discomfort and flatulence. Mild to moderate hypersensitivity reactions were reported in 0.3 percent of patients treated with VELTASSA and included edema of the lips.

For additional Important Safety Information and VELTASSA’s full Prescribing Information, please visit [http://www.relypsa.com/veltassa/prescribing-information/](http://www.relypsa.com/veltassa/prescribing-information/)