VELTASSA® (patiromer) for Oral Suspension

VELTASSA® is a non-absorbed polymer medicine approved by the U.S. Food and Drug Administration (FDA) in October 2015, making it the first approved medicine for the treatment of hyperkalemia in more than 50 years.[1]

Since approval, the real-world patient experience with VELTASSA has exceeded 5 million patient-treatment days.

What is VELTASSA?

VELTASSA® (patiromer) is a once-daily, sodium-free potassium binder prescription medication taken orally, with or without food, for the treatment of high potassium (hyperkalemia). VELTASSA should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

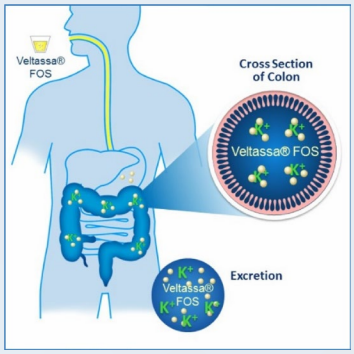
Please see Important Safety Information & Limitations of Use for VELTASSA on the following page. Please visit www.VELTASSA.com for more information, including the full Prescribing Information.

About Hyperkalemia

Hyperkalemia is generally defined as blood potassium levels of >5.0 mEq/L.[2] If not treated, some people with hyperkalemia can be at risk for abnormal heart rhythms and sudden death.[2]

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.[3] The potassium is then excreted from the body through the normal colonic 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. Clinical studies[4] further support VELTASSA's potential for chronic use in hyperkalemic patients with CKD and type 2 diabetes who are taking RAAS inhibitor therapy.

- ☑ **The Phase 2 AMETHYST-DN trial** evaluated use of VELTASSA over 52 weeks in 306 hyperkalemic patients with CKD and type 2 diabetes who were taking RAAS inhibitors. Throughout the year-long study, the majority of patients (ranging from 77.4 - 92.7 percent) had potassium levels in the target range (3.8-5.0 mEq/L).[5]
- ☑ **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 the 237 patients evaluated 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; $p<0.001$).[6]
- ☑ **The Phase 4 TOURMALINE trial** randomly assigned 114 patients with blood potassium levels greater than 5.0 mEq/L to receive VELTASSA once-a-day at a starting dose of 8.4 g either with or without food. There was no statistically significant difference in the percentage of patients achieving serum potassium levels within the target range (3.8-5.0 mEq/L) between the groups taking VELTASSA with or without food at either week 3 or week 4.[7]
- ☑ **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).[8]

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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:

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 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% of patients treated with VELTASSA. Approximately 9% of patients in clinical trials developed hypomagnesemia with a serum magnesium value <1.4 mg/dL. Monitor serum magnesium. Consider magnesium supplementation in patients who develop low serum magnesium levels.

Adverse Reactions:

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

Please see full Prescribing Information.

References

1 Sterns, RH. Ion-exchange resins for the treatment of hyperkalemia: are they safe and effective? *J Am Soc Nephrol.* 2010; 21(5):733-5.
2 Rastegar A, Soleimani M. Hypokalaemia and hyperkalaemia. *Postgrad Med J.* 2001; 77:759-764.
3 Relypsa. About Veltassa. https://www.veltassa.com/patient/about-veltassa/. Accessed May 29, 2018.
4 Pooled analysis of AMETHYSY, OPAL, TOURMALINE announced at 2018 NKM Spring Meeting http://www.relypsa.com/file.cfm/143/docs/RLYP_News_2018_4_11_Release.pdf
5 Bakris, GL. Effect of Patiromer on Serum Potassium Level in Patients With Hyperkalemia and Diabetic Kidney Disease: The AMETHYST-DN Randomized Clinical Trial. *JAMA.* 2015; 314(2):151-61
6 Weir, MR. Patiromer in Patients with Kidney Disease and Hyperkalemia Receiving RAAS Inhibitors. *N Engl J Med.* 2015; 372:211-221
7 Pergola, PE. Patiromer Lowers Serum Potassium When Taken without Food: Comparison to Dosing with Food from an Open-Label, Randomized, Parallel Group Hyperkalemia Study. *Am J Nephrol.* 2017; 46:323-332
8 Veltassa Prescribing Information. Section 6.1 Clinical Trials Experience. Table 1.

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