FDA News Release

FDA approves new drug to treat hyperkalemia

For Immediate Release

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Release

The U.S. Food and Drug Administration today approved Veltassa (patiromer for oral suspension) to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high.

“Too much potassium in the blood can lead to dangerous, even fatal, changes in heart rhythm,” said Norman Stockbridge, M.D., Ph.D., director of the Division of Cardiovascular and Renal Products in the FDA’s Center for Drug Evaluation and Research. “It is important to have treatment options for hyperkalemia available to patients.”

Potassium, a mineral that is delivered to the body by food, is needed for cells to function properly. The kidneys remove potassium from the blood to maintain a proper balance of potassium in the body. But when the kidneys are not able to remove enough potassium from the blood, the level of potassium can get too high. Hyperkalemia typically occurs in patients with acute or chronic kidney disease or heart failure, particularly in those who are taking drugs that inhibit the renin-angiotensin-aldosterone system, which regulates blood pressure and fluid balance in the body.

Veltassa, a powdered medication that patients mix with water and take by mouth, works by binding potassium in the gastrointestinal tract, decreasing its absorption. In clinical trials, Veltassa was effective in lowering potassium levels in hyperkalemic participants with chronic kidney disease on at least one drug that inhibited the renin-angiotensin-aldosterone system.
In clinical trials, the most common adverse reactions reported by participants taking Veltassa were constipation, decreased magnesium levels in the blood (hypomagnesemia), diarrhea, nausea, abdominal discomfort, and flatulence. The use of Veltassa is not appropriate for rapid correction of severe hyperkalemia because lowering of serum potassium may take hours to days.

Veltassa has a boxed warning because it binds many other orally administered drugs, which could decrease their absorption and reduce their effects. The warning recommends taking it and any other orally administered medication at least six hours apart. The drug must be dispensed with a patient Medication Guide that describes important information about its uses and risks.

Veltassa is manufactured by Relypsa Inc. of Redwood City, California.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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**Inquiries**

**Media**

☑️ Sandy Walsh (mailto:sandy.walsh@fda.hhs.gov)

📞 301-796-4669

**Consumers**

📞 888-INFO-FDA

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