Uploaded to the VFC Website

2016

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

If Veterans don't help Veterans, who will?

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members & subscribers.

Tresiba and Ryzodeg approved to improve blood sugar control in adults with diabetes mellitus

Published on October 9, 2015 at 3:09 AM

The U.S. Food and Drug Administration today approved Tresiba (insulin degludec injection) and Ryzodeg 70/30 (insulin degludec/insulin aspart injection) to improve blood sugar (glucose) control in adults with diabetes mellitus.

According to the Centers for Disease Control and Prevention, approximately 21 million people in the United States have been diagnosed with diabetes. Over time, diabetes increases the risk of serious health complications, including heart disease, blindness, nerve and kidney damage. Improvement in blood sugar control can reduce the risk of some of these long-term complications.

"Long-acting insulins play an essential role in the treatment of patients with type-1 diabetes and in patients with type-2 diabetes with advanced disease," said Jean-Marc Guettier, M.D., director of the Division of Metabolism and Endocrinology Products in the FDA's Center for Drug Evaluation and Research. "The FDA remains committed to support the development of innovative therapies for the treatment of diabetes."

Tresiba is a long-acting insulin analog indicated to improve glycemic control in adults with type 1 and 2 diabetes mellitus. Dosing of Tresiba should be individualized based on the patient's needs. Tresiba is administered subcutaneously once daily at any time of day.

The efficacy and safety of Tresiba used in combination with mealtime insulin for the treatment of patients with type-1 diabetes were evaluated in two 26-week and one 52-week active-controlled clinical trials involving 1,102 participants exposed to Tresiba. The efficacy and safety of Tresiba used in combination with mealtime insulin or used as add-on to common background oral antidiabetic drugs for the treatment of patients with type-2 diabetes were evaluated in four 26-week and two 52-week active-controlled clinical trials involving 2,702 participants exposed to Tresiba. In participants with type 1 and 2 diabetes who had inadequate blood sugar control at trial entry, treatment with Tresiba provided reductions in HbA1c (hemoglobin A1c or glycosylated hemoglobin, a measure of blood sugar control) in line with reductions achieved with other, previously approved long-acting insulin.

Ryzodeg 70/30 is a mixture of insulin degludec, a long-acting insulin analog, and insulin aspart, a rapid-acting human insulin analog. It is indicated to improve glycemic control in adults with diabetes mellitus.

The efficacy and safety of Ryzodeg 70/30 used in combination with mealtime insulin for the treatment of patients with type 1 diabetes were evaluated in one 26-week active controlled clinical trial involving 362 participants exposed to Ryzodeg 70/30. The efficacy and safety of Ryzodeg 70/30 administered once or twice daily for the treatment of patients with type 2 diabetes were evaluated in four active controlled 26-week clinical trials involving 998 participants exposed to Ryzodeg 70/30. In participants with type 1 and 2 diabetes who had inadequate blood sugar control at trial entry, treatment with Ryzodeg 70/30 provided reductions in HbA1c equivalent to reductions achieved with other, previously approved long-acting or pre-mixed insulin.

Tresiba and Ryzodeg should not be used in those who have increased ketones in their blood or urine (diabetic ketoacidosis). Patients or caregivers should monitor blood glucose in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision. Tresiba and Ryzodeg may cause low blood sugar (hypoglycemia), which can be life-threatening. Patients should be monitored more closely with changes to insulin dosage, co-administration of other glucose-lowering medications, meal pattern, physical activity, and in patients with renal impairment or hepatic impairment or hypoglycemia unawareness.

Severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock may occur with any insulin.

The most common adverse reactions associated with Tresiba and Ryzodeg in clinical trials were hypoglycemia, allergic reactions, injection site reactions, pitting at the injection site (lipodystrophy), itching, rash, edema, and weight gain.

Tresiba and Ryzodeg are manufactured by Novo Nordisk in Plainsboro, New Jersey.

Saved from URL: http://www.news-medical.net/news/20151009/Tresiba-and-Ryzodeg-approved-to-improve-blood-sugar-control-in-adults-with-diabetes-mellitus.aspx

Source:
http://www.fda.gov