Generic Name:
Insulin degludec injection, insulin degludec/insulin aspart injection
Trade Name:
Tresiba, Ryzodeg 70/30
Company:
Novo Nordisk
Notes:

FDA has approved insulin degludec injection under the trade name Tresiba and insulin degludec/insulin aspart injection under the trade name Ryzodeg 70/30 to improve blood glucose control in adults with diabetes.

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

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.

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 glycosylated hemoglobin (A1C) 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.

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.

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 glucose control at trial entry, treatment with Ryzodeg 70/30 provided reductions in A1C 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 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 hypoglycemia, which can be life-threatening. Patients should be monitored more closely with changes to insulin dosage, coadministration 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.

Medication Monitor Categories:
New Drug Approvals
