Generic Name:  
Insulin lispro injection  
Trade Name:  
Admelog  
Company:  
Sanofi-Aventis U.S.  
Notes:

**FDA has approved** insulin lispro injection, a short-acting insulin indicated to improve control in blood glucose levels in adults and pediatric patients aged 3 years and older with type 1 diabetes and adults with type 2 diabetes. It is the first short-acting insulin approved as a “follow-on” product, submitted through the agency’s 505(b)(2) pathway.

Approval was based on two Phase III clinical trials that enrolled approximately 500 patients in each.

The agent can be administered by S.C. injection, S.C. infusion (i.e., via insulin pump), or I.V. infusion. Dosing should be individualized according to route of administration and the patient’s metabolic needs, blood glucose monitoring results, and glycemic control goal.

The most common adverse reactions in clinical trials were hypoglycemia, itching, and rash. Other potential adverse reactions include allergic reactions, injection site reactions, and lipodystrophy.

Insulin lispro injection should not be used during episodes of hypoglycemia or in patients with hypersensitivity to insulin lispro or one of its ingredients. In addition, the prefilled pens or syringes must never be shared between patients, even if the needle is changed.

Patients or caregivers should monitor blood glucose in all patients treated with insulin products. Insulin regimens should be modified cautiously and only under medical supervision. Insulin lispro injection 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, and physical activity, as well as with renal impairment or hepatic impairment or hypoglycemia unawareness.

Accidental mix-ups between insulin products can occur. Patients should check insulin labels before injecting the insulin product.

Severe, life-threatening, generalized allergic reactions, including anaphylaxis, may occur.

Health care providers should monitor potassium levels in patients at risk of hyperkalemia.

**Medication Monitor Categories:**

**New Drug Approvals**