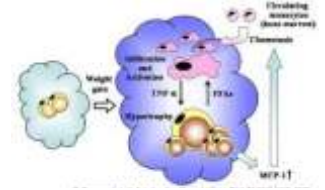


Rx INSULIN ANALOG

(Lantus (insulin glargine [rDNA origin] injection))



Drug Name: Lantus (insulin glargine [rDNA origin] injection)

Approval Status: Approved April 2000

Treatment Area: For adults and children w/Type 1 diabetes, or adults w/Type 2 diabetes requiring basal insulin to control hyperglycemia

General Information

Lantus is the first FDA approved long-acting (basal) recombinant human insulin analog with a once-daily administration and a 24-hour glucose-lowering effect. This biosynthetic insulin, injected subcutaneously and designed to mimic NPH human insulin, is indicated for both adult and pediatric patients with Type 1 diabetes. It may also be used for the treatment of adults with Type 2 diabetes who require basal insulin for the control of hyperglycemia.

The chemical structure of Lantus allows for regulated release of the insulin into the circulation with a glucose-lowering effect over a 24-hour period. In clinical studies, no specific pronounced peak was detected over this period.

Clinical Results

In clinical studies, the efficacy of Lantus, measured by metabolic control, was comparable to **NPH** human insulin. In addition, Lantus had a slower absorption rate than NPH human insulin. This absorption allowed for a relatively constant concentration/time profile over 24-hours. The glucose-lowering effect was detected over the entire 24-hour period.

Side Effects

As with other insulin therapies, Lantus can cause the following side effects (with hypoglycemia being the most common adverse effect):

- * Hypoglycemia
- * Worsening of diabetic retinopathy
- * Lipodystrophy
- * Skin reactions (such as injection-site reaction, pruritus, and rash)*
- * Allergic reactions
- * Sodium retention
- * Edema

*In clinical trials, patients treated with Lantus had a higher incidence of injection-site pain (2.7%) than did patients receiving NPH human insulin (0.7%). In general, the reports of pain were mild and did not require discontinuation of treatment with the insulin therapy.

All patients with diabetes should have regular glucose monitoring.

Mechanism of Action

The primary activity of insulin, including insulin glargine, is regulation of glucose metabolism. Insulin and its analogs lower blood glucose levels by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis in the adipocyte, inhibits proteolysis, and enhances protein synthesis.
(From FDA Label)

Additional Information

Visit the Sanofi-aventis web site to learn more about Lantus and about other products, research, and services provided by the company that developed this drug.

To learn more about diabetes in adults and children, and treatments for this disease, visit the web sites of the American Diabetes Association and the Juvenile Diabetes Foundation International.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.

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