

Convenient Initiation, Ultimate Outcome





Solution

For Injection in a pre-filled pen

Glaine® as a long-acting Insulin, is a relatively simple protein and well characterized molecule, differs from human insulin in that the amino acid asparagine at the position 21 is replaced by glycine and two arginines are added to the C terminus of the B-chain. Insulin glargine is produced by recombinant DNA technology utilizing a non-pathogenic laboratory strain of Escherichia coli.

The primary activity of Insulin, including Insulin Glargine, is regulation of glucose metabolism. Adequate insulin dosage permits patients with diabetes to effectively utilize carbohydrates, proteins and fats. Regardless of dose strength, insulin enables carbohydrate metabolism to occur and thus to prevent the production of ketone bodies by the liver. Some patients develop severe insulin resistance such that daily doses of several hundred units of insulin or more are required. Insulin and its analogues 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.

Glaine® differs from other Insulins because its unique structure provides a smooth and peak less profile with a prolonged duration of action of 24 hours (end of observation period) compared to 14.5 hours for NPH human Insulin.

After subcutaneous injection of Glaine[®], the Insulin serum concentrations indicate a slower, more prolonged absorption and a lack of a peak in comparison to NPH human Insulin. Concentrations are thus consistent with the time profile of the pharmacodynamics activity of Insu-

Glaine® is formulated to have a low aqueous solubility at neutral pH. Glaine® has a pH of 4 and at this pH is completely soluble. After injection into the subcutaneous tissue, the acidic solution is neutralized leading to formation of micro-precipitates from which small amounts of Insulin are slowly released providing a smooth peak-less predictable time/concentration profile and prolonged duration of action. This allows once daily dosing relatively constant concentration of a 24 hours to meet a patient's basal insulin needs. In contrast to other insulin products the duration of action of Glaine®, as an Insulin glairgine was similar after subcutaneous injection into abdominal, deltoid, or tight areas. Glaine® can be used to treat adults with type 2 diabetes and adults and pediatric patients (children 6 years and older) with type 1 diabetes for the control of high blood sugar but should not be used to treat diabetic ketoacidosis.

Glaine® is available in the pack of 1 pre-filled pen of 3 mL and pack of 5 pre-filled pens of 3mL. It is compatible with Yepsomed Clickfine® Needles & BD Ultra-FineTM Pen Needles.



Quality to Life