

# Lantus (Insulin Glargine) Biosimilar Clinical Trial & Opportunity Insight

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## Abstracts

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“Lantus (Insulin Glargine) Biosimilar Clinical Trial & Opportunity Insight” report by PNS Pharma gives comprehensive clinical insight on 37 biosimilar version of Lantus drug in clinical pipeline. Currently 5 biosimilar version of Lantus are commercially available in India, Japan, Kenya, Czech Republic, Estonia, Germany, China, Slovakia, United Kingdom for the treatment of Type 1 & 2 diabetes mellitus. The patent on Lantus expired in 2014.

Lantus is the brand name for Insulin Glargine, a man made form of hormone generally produced in the human body, used in the treatment of diabetes mellitus in children and adults. The long lasting process of insulin works to lower down the levels of glucose (sugar) in blood. Lantus is also used to treat type 2 & type 1 diabetes in adults and children having more than 6 years of age. The drug usually starts working after several hours of injection and keeps performing for 18-26 hours or more without any pronounced peak.

Lantus is a package consisting of a sterile solution of insulin glargine containing zinc, m-cresol, glycerol 85%, polysorbate and water for injection as inactive ingredients. Each milliliter of Lantus contains 100 Units (3.6378mg) of insulin glargine. The pH of Lantus is adjusted by addition of hydrochloric acid and sodium hydroxide. It has a pH value of approximately 4 making it completely soluble. It is produced by recombinant DNA technology using a non-pathogenic laboratory strain of Escherichia coli (K12) acting as production organism. Chemical representation of insulin glargine present in Lantus is 21A-Gly-30Ba-L-Arg-3030b-L-Arg-human insulin and empirical formula as C<sub>267</sub>H<sub>404</sub>N<sub>72</sub>O<sub>78</sub>S<sub>6</sub> and a molecular weight of 6063.

The key function of Lantus consisting insulin is to regulate blood sugar levels is performed by stimulating peripheral glucose uptake by skeletal muscle and fat and by inhibiting hepatic glucose production. Lantus consists of a substitution of glycine as asparagine at N21 combining with 2 additional arginines to the carboxy terminal of B chain. The arginine amino acids are responsible for shifting the isoelectric point to 5.4 to 6.7, making the molecule more soluble in acidic pH and less soluble in physiological pH. This shift allows a subcutaneous injection of a clear solution.

Lantus treatment demands for daily dosage as injection under the skin into the subcutaneous tissue and not intravenously or by using insulin pumps. The injection is to be taken once in day time followed by 1 injection each day at the same time. The dosage is adjusted according to individual's physical activity, severe conditions of illness and changes in food intake. It is injected into abdominal area, thigh and deltoid. The place to inject can be replaced within the region to reduce the risk of side effects.

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