FIRST TIME GENERIC APPROVAL

Brand Name	Insulin glargine
Generic Name	insulin glargine-yfgn
Drug Manufacturer	Mylan Specialty L.P.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

July 28, 2021

LAUNCH DATE

3rd Quarter of 2021

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Biologic License Application (BLA): 761201

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Insulin glargine injection is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

Limitations of Use: Not recommended for treating diabetic ketoacidosis.

MECHANISMS OF ACTION

The primary activity of insulin, including insulin glargine products, is regulation of glucose metabolism. Insulin and its analogs lower blood glucose by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis and proteolysis and enhances protein synthesis.

DOSE FORM AND STRENGTH

Injection: 100 units/mL (U-100) available as:

- 10 mL multiple-dose vial.
- 3 mL single-patient-use prefilled pen.

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DOSE & ADMINISTRATION

- Individualize dosage based on metabolic needs, blood glucose monitoring, glycemic control, type of diabetes, prior insulin use.
- Administer subcutaneously into the abdominal area, thigh, or deltoid once daily at any time of day, but at the same time every day.
- Do not dilute or mix with any other insulin or solution.
- Rotate injection sites to reduce the risk of lipodystrophy and localized cutaneous amyloidosis.
- Closely monitor glucose when changing to insulin glargine products and during initial weeks thereafter.