FIRST TIME GENERIC APPROVAL

Brand Name	Tresiba®
Generic Name	insulin degludec
Drug Manufacturer	Novo Nordisk Pharma, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

July 1, 2022

LAUNCH DATE

N/A

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Biologic License Application (BLA): 203314

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Insulin degludec is a long-acting human insulin analog indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus.

MECHANISMS OF ACTION

The primary activity of insulin, including Insulin degludec, 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 also inhibits lipolysis and proteolysis and enhances protein synthesis. Insulin degludec forms multi-hexamers when injected into the subcutaneous tissue resulting in a subcutaneous insulin degludec depot. The protracted time action profile of Insulin degludec is predominantly due to delayed absorption of insulin degludec from the subcutaneous tissue to the systemic circulation and to a lesser extent due to binding of insulin-degludec to circulating albumin.

DOSE FORM AND STRENGTH

Injection: Available as:

- 100 units/mL (U-100): 3 mL single-patient-use FlexTouch® prefilled pen.
- 100 units/mL (U-100): 10 mL multiple-dose vial.
- 200 units/mL (U-200): 3 mL single-patient-use FlexTouch® prefilled pen.

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DOSE & ADMINISTRATION

- Inject Insulin degludec subcutaneously into the thigh, upper arm, or abdomen.
- Rotate injection sites to reduce risk of lipodystrophy and localized cutaneous amyloidosis.
- For pediatric patients requiring less than 5 units of Insulin degludec each day, use an Insulin degludec U-100 vial.
- In adults, inject subcutaneously once daily at any time of day.
- In pediatric patients inject subcutaneously once daily at the same time every day.
- Individualize dose based on type of diabetes, metabolic needs, blood glucose monitoring results and glycemic control goal.
- The recommended days between dose increases are 3 to 4 days.