



### Tresiba® (insulin degludec) – Expanded Indication

- On December 19, 2016, [Novo Nordisk](#) announced the FDA approval of [Tresiba \(insulin degludec\)](#) to improve glycemic control in patients 1 year of age and older with diabetes mellitus.
  - Previously, Tresiba was indicated for treatment in adult patients.
  - Tresiba is not recommended for treating diabetic ketoacidosis.
  - Tresiba is not recommended for pediatric patients requiring < 5 units of Tresiba.
- Tresiba's expanded indication is based on the BEGIN™ Young 1 clinical study of 350 patients 1 to 17 years of age with type 1 diabetes mellitus (T1DM) randomized to Tresiba or [Levemir® \(insulin detemir\)](#) for 26 weeks.
  - At week 26, the difference in HbA1c reduction from baseline between Tresiba and Levemir was 0.15% (95% CI: -0.03, 0.33) and met the pre-specified non-inferiority margin of 0.4%.
  - The use of Tresiba in patients ≥ 1 year of age with type 2 diabetes mellitus (T2DM) is also supported by evidence from adequate and well-controlled studies in adults with T2DM.
- The recommended dose of Tresiba in pediatric patients should be injected subcutaneously (SC) once-daily at the same time every day.
  - In adults, Tresiba may be injected SC once-daily at any time of the day.
  - Consult the prescribing information for recommended starting doses for pediatric and adult patients with T1DM and T2DM.
  - Individualize and titrate the dose of Tresiba based on the patient's metabolic needs, blood glucose monitoring results, and glycemic control goal.
  - Dose increases should occur every 3 - 4 days.



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