Abbreviated prescribing information

Tresiba® (insulin degludec) 100U and 200U (100 units/mL or 200 units/mL insulin solution for injection) in a pre-filled pen (FlexTouch®). Tresiba® 100U solution for injection in a cartridge (Penfill®).

Consult Summary of Product Characteristics before prescribing. **Presentation:** Tresiba® FlexTouch® Tresiba® Penfill®. All presentations contain insulin degludec. Tresiba® 100 units/mL – 1 mL of solution contains 100 units insulin degludec (equivalent to 3.66mg). One pre-filled device or one cartridge contains 300 units of insulin degludec in 3 mL solution. Tresiba® 200 units/mL – 1 mL of solution contains 200 units insulin degludec (equivalent to 7.32mg). One pre-filled device contains 600 units of insulin degludec in 3 mL solution. **Indications:** Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year. **Posology and administration:** Tresiba® is a basal insulin for once-daily subcutaneous administration any time of the day, preferably at the same time of day. On occasions when administration at the same time of the day is not possible, Tresiba® allows for flexibility in the timing of insulin administration. A minimum of 8 hours between injections should be ensured. In patients with type 2 diabetes mellitus, Tresiba® can be administered alone, or in any combination with oral antidiabetic medicinal products, GLP-1 receptor agonists and bolus insulin. In type 1 diabetes mellitus, Tresiba® must be used with short-/rapid-acting insulin. Administration by subcutaneous injection only. Tresiba® is available in 100 units/mL and 200 units/mL. For Tresiba® 100 units/mL a dose of 1–80 units per injection, in steps of 1 unit, can be administered. For Tresiba® 200 units/mL a dose of 2–160 units per injection, in steps of 2 units, can be administered. The dose counter shows the number of units regardless of strength. No dose conversion should be done when transferring a patient to a new strength. When initiating patients with type 2 diabetes mellitus, the recommended daily starting dose is 10 units followed by individual dosage adjustments. Transferring from other insulins; in type 2 diabetes changing the basal insulin to Tresiba® can be done unit-to-unit, based on the previous basal insulin component, and when transferring from a twice-daily regimen or from insulin glargine (300 units/mL) a dose reduction of 20% should be considered; in type 1 diabetes, a dose reduction of 20% based on the previous insulin dose or basal component of a continuous subcutaneous insulin infusion should be considered with subsequent individual dosage adjustments. Doses and timing of concomitant treatment may require adjustment. Using Tresiba® in combination with GLP-1 receptor agonists in patients with type 2 diabetes mellitus; when adding Tresiba® to GLP-1 receptor agonists, the recommended daily starting dose is 10 units; when adding GLP-1 receptor agonists to Tresiba®, it is recommended to reduce the dose of Tresiba® by 20% to minimize the risk of hypoglycaemia. In all cases, doses should be adjusted based on individual patients' needs; fasting plasma glucose is recommended to be used for optimising basal insulin doses. In elderly patients and patients with renal/hepatic impairment, glucose monitoring should be intensified, and the dose adjusted on an individual basis. In paediatric population, when changing basal insulin to Tresiba®, dose reduction of basal and bolus insulin needs to be considered on an individual basis in order to minimise the risk of hypoglycaemia. Tresiba® comes in a pre-filled pen, FlexTouch® (2 concentrations) or cartridge, Penfill®, designed to be used with NovoFine®/NovoTwist® needles and for Penfill® Novo Nordisk insulin delivery systems. **Contraindications:** Hypersensitivity to the active substance or any of the excipients. **Special warnings and precautions:** Too high insulin dose, omission of a meal or unplanned strenuous physical exercise may lead to hypoglycaemia. In children, care should be taken to match insulin doses (especially in basal-bolus regimens) with food intake and physical activities in order to minimize the risk of hypoglycaemia. Reduction of warning symptoms of hypoglycaemia may be seen upon tightening control and also in patients with long-standing diabetes. Administration of rapid-acting insulin is recommended in situations with severe hyperglycaemia. Inadequate dosing and/or discontinuation of treatment in patients requiring insulin may lead to hyperglycaemia and potentially to diabetic ketoacidosis. Concomitant illness, especially infections, may lead to hyperglycaemia and thereby cause an increased insulin requirement. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. Transferring to a new type, brand or manufacturer of insulin should be done under medical supervision and may result in a change in dosage. When using insulin in combination with pioglitazone, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. Patients must be instructed to always check the insulin label before each injection to avoid accidental mix-ups between the two strengths of Tresiba® and other insulins. Hypoglycaemia may constitute a risk when driving or operating machinery. **Pregnancy and lactation:** Treatment with Tresiba® may be considered during pregnancy, if clinically needed. Intensified blood glucose control and monitoring are recommended throughout pregnancy and while contemplating pregnancy. There is no clinical experience with Tresiba® during breast-feeding. It is unknown whether insulin degludec is excreted in human milk. No metabolic effects are anticipated in the breast-fed newborn/infant. **Undesirable effects:** Refer to SmPC for complete information on side effects. Very common (≥1/10); common (≥1/100 to < 1/10); uncommon (≥1/1000 to < 1/100); rare (≥ 1/10000 to < 1/1000); very rare (< 1/10000); not known (cannot be estimated from the available data). Very common: Hypoglycaemia. Common: Injection site reactions. Uncommon: Lipodystrophy and peripheral oedema. Rare: Hypersensitivity and urticaria. Not known: Cutaneous amyloidosis. With insulin preparations, allergic reaction may occur; immediate-type allergic reactions may potentially be life-threatening. Injection site reactions are usually mild, transitory, and normally disappear during continued treatment. **Marketing authorisation numbers :** EU/1/12/807/1-10, EU/1/12/807/12-13 and EU/1/12/807/15-16. **Legal category:** Prescription-only medicine (POM). **Marketing authorisation holder:** Novo Nordisk A/S Novo Allé DK-2880 Bagsværd Denmark. **Date of Review of Prescribing Information:** February 2022. **Summary of Product Characteristics** can be obtained from Novo Nordisk A/S. **HQ22TSM00002**