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Start your patient with TRESIBA®: Ultra-long duration of action[1,2]

- Successful reductions in HbA_{1C}[3,4]
- Significantly lower risk of hypoglycaemia versus glargine U100 [5-7]
- Flexibility in day-to-day dosing time when needed[1]
- Significantly lower day-to-day variability in glucose-lowering effect vs glargine U100 and U300 [8,9]
- Approved for a broad range of patients[1#]

* Once daily (OD) plus additional antidiabetic treatments in accordance with standard of care. # Treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year, elderly patients, renal and hepatic impairment patients.

Abbreviated prescribing information Tresiba® (insulin degludec) 100U (100 units/mL insulin solution for injection in a prefilled pen (FlexTouch®). **Please consult the full prescribing information before prescribing.**

Presentation: Tresiba® FlexTouch® 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 contains 300 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. The dose is 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 a short-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 times of concurrent treatment may require adjustment. Using Tresiba® in combination with GLP-1 receptor agonists in patients with type 2 diabetes mellitus, where adding Tresiba® to GLP-1 receptor agonists, the recommended daily starting dose is 16 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 optimizing 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® designed to be used with NovoFine® or NovoTwist® injection needles. **Contraindications:** Hypersensitivity to the active substance or any of the excipients. **Special warnings and precautions:** Too high a dose in dose, omission of a meal or unplanned vigorous physical exercise may lead to hypoglycaemia. In children, care should be taken to match insulin dose with meals, and possible and physical activities in order to minimize the risk of hypoglycaemia. Reduction of warning symptoms of hypoglycaemia may be seen upon lengthening control and also in patients with long-standing diabetes. Administration of insulin-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 usually 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 amyloidosis. Transferring to another 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 thiazolidinediones, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Thiazolidinediones 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-up between the two strengths of Tresiba® and other insulins. Hypoglycaemia may severely impair, when driving or operating machinery. **Pregnancy and lactation:** There is no clinical experience with use of Tresiba® in pregnant women and during breastfeeding. Animal reproduction studies have not revealed any difference between insulin degludec and human insulin regarding embryotoxicity and teratogenicity. **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 (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000). Not known (cannot be estimated from the available data). Very common: Hypoglycaemia. Common: Injection site reactions, Dircomfort, Lipodystrophy and peripheral oedema. Rare: Hypersensitivity and urticaria. Withdrawn: In preparations of 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. **Date of Review:** December 2021

References: 1. Tresiba® Package Insert. 2. Jonassen I, Havelund S, Hoeg-Jensen T, et al. Design of the novel protraction mechanism of insulin degludec, an ultra-long-acting basal insulin. Pharmaceutical Research 2012;29(8):2104-14. 3. Rodbard HW, Cheng B, Zeman B, Rasmussen AT, et al. Comparison of insulin degludec with insulin glargine in insulin-naive subjects with type 2 diabetes: a 2-year randomized, treat-to-target trial (BEGIN: Basal-Bolus Type 2). Diabetes Obes Metab 2013;15(12):1098–105. 4. Riddle MW, Rosenstock J, Gerich J; Insulin Glargine 4002 Study Investigators. The treat-to-target trial: randomized addition of glargine or human NPH insulin to oral therapy of type 2 diabetic patients. Diabetes Care 2003;26(11):3080–6. 5. Gerstein HC, Bosch J, Dagenais GR, et al; ORIGIN Trial Investigators. Basal insulin and cardiovascular and other outcomes in dysglycemia. N Engl J Med 2012;367(4):319–28. 6. Marso SP, Mcguire DK, Zinman B, Poulter NR, Emerson SS, Pieber TR, Pratley RE, Haahr PM, Lange M, Brown-Frandsen K, Moses A, Skibsted S, Kvist K, Buse JB for the DEVOTE Study Group. Efficacy and safety of degludec versus glargine in type 2 diabetes. New England Journal of Medicine 2017; 377:723–732. 7. Wysham C,Bhargava A, Chaykin L, de la Rosa R, Handelsman Y, Troelsen L, Kvist K, Nowotny I. Effect of insulin degludec vs insulin glargine U100 on hypoglycaemia in Patients With Type 2 Diabetes: The SWITCH 2 Randomized Clinical Trial. JAMA 2017; 318(1):45–56. 8. Lane W, Bailey TS, Gerety G, Gumprecht J, Hale P, Shimkaveg G, Hansen CT, Nielsen TSS, Warren M. Effect of Insulin Degludec vs Insulin Glargine U300 on Hypoglycemia in Patients With Type 1 Diabetes: The SWITCH 1 Randomized Clinical Trial. JAMA 2017; 318(1):33–44. 9. Riese F, Hermansen K, Nosek L, Hollmann M, Rasmussen S, Haahr H. Insulin degludec: two times lower pharmacodynamic variability than insulin glargine under euglycaemic conditions in type 1 diabetes. Diabetes, Obesity and Metabolism 2011; 13(10):932–938.

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TRESIBA®

insulin degludec [rDNA origin] injection