Prescribing Information

Tresiba®▼
Insulin degludec.

Tresiba® FlexTouch® 100 units/mL
Tresiba® FlexTouch® 200 units/mL
Tresiba® Penfill® 100 units/mL
All presentations contain insulin degludec.
Tresiba® 100 units/mL - 1 mL of solution contains 100 units insulin degludec (equivalent to 3.66 mg). One pre-filled device or one cartridge contains 300 units of insulin degludec in 3mL solution. Tresiba® 200 units/mL - 1 mL of solution contains 200 units insulin degludec (equivalent to 7.32 mg). One pre-filled device contains 600 units of insulin degludec in 3mL solution.
Indication: Treatment of diabetes mellitus in adults.
Posology and administration: Tresiba® is a basal insulin for once-daily subcutaneous administration, any time of day preferably at the same time of day. On occasions when not administered at the same time of day, a minimum of 8 hours between injections should be ensured. One unit (U) of insulin degludec corresponds to 1 international unit (IU) of human insulin, 1 unit of insulin glargine/insulin detemir. If a dose is forgotten, the dose should be taken on discovery and usual once daily dosing should then be resumed. In patients with type 2 diabetes mellitus Tresiba® can be used alone, in combination with oral antidiabetic medicinal products or with a bolus insulin; the recommended starting dose is 10 units. In type 1 diabetes mellitus, Tresiba® is to be used once-daily and must be combined with short/rapid-acting insulin. Tresiba® is available in 100 units/mL and 200 units/mL. For the 100 units/mL a dose of 1-80 units per injection, in steps of 1 unit can be administered; for the 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 to a new strength. During transfer 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; in type 1 diabetes the same applies as for type 2 diabetes apart from where transferring from twice-daily basal insulin or patients with an HbA1c <8.0%, the Tresiba® dose needs to be determined on an individual basis with a dose reduction considered. Doses /times of concomitant treatment may require adjustment. In all cases doses should be adjusted based on individual patients' needs; fasting plasma glucose is recommended to be used for optimising glycaemic control. In elderly patients and patients with renal/hepatic impairment glucose monitoring should be intensified and the dose adjusted on an individual basis. The safety/efficacy of Tresiba® has not been established in adolescents/children below 18 yrs. of age. Tresiba® must not be administered intravenously, intramuscularly or in insulin infusion pumps. It should be administered subcutaneously in the thigh, upper arm or abdominal wall; injection sites should be rotated. Adjustment of dose may be necessary if patients undertake increased physical activity, change their diet or during concomitant illness. 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 to any of the excipients.
Special warnings and precautions for use: Too much insulin, omission of a meal or unplanned strenuous exercise may lead to hypoglycaemia. Reduction of warning symptoms of hypoglycaemia may be seen upon tightening control and also in patients with long-standing diabetes. As with any basal insulin, the prolonged effect of Tresiba® may delay recovery from hypoglycaemia. Administration of rapid-acting insulin is recommended in situations with severe hyperglycaemia. Use of inadequate doses or discontinuation of treatment may lead to hyperglycaemia and ketoacidosis which are potentially lethal. Transferring to a new type, brand or manufacturer of insulin should be done under strict medical supervision. Cases of cardiac failure reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure; if the combination is used, 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. Intensification of insulin therapy with sudden improvement in glycaemic control may be associated with a temporary worsening of diabetic retinopathy. Patients must be instructed to check the insulin label before each injection to avoid accidental mix-ups between the two strengths of Tresiba® and other insulins. Patients who are blind/have poor vision must get assistance from another person with good vision who is trained in using the insulin device. Insulin administration may cause antibodies to form; due to the presence of antibodies in rare cases adjustment of dose may be necessary. Hypoglycaemia may constitute a risk when driving or operating machinery. Patients must be advised to take precautions to avoid hypoglycaemia while driving. Tresiba® must not be mixed with other medicinal products.
Fertility, pregnancy and lactation: There is no clinical experience with use of Tresiba® in pregnant women and during breast feeding. Animal reproduction studies with insulin degludec have not revealed any adverse effects on fertility.
Undesirable effects: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 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. Uncommon: Lipodystrophy and peripheral oedema. Rare: Hypersensitivity and urticaria. With insulin preparations, allergic reactions may occur; immediate-type allergic reactions may potentially be life threatening. Injection site reactions are usually mild, transitory and normally disappear during continued treatment. The Summary of Product Characteristics should be consulted for a full list of side effects.
MA numbers and Basic NHS Price: 5 x 3 ml 100 U/mL Penfill® EU/1/12/807/007 £72.00; 5 x 3 ml 100 U/mL FlexTouch® EU/1/12/807/004 £72.00; 3 x 3 ml 200 U/mL FlexTouch® EU/1/12/807/013 £86.40.
Legal category: POM.
Full prescribing information can be obtained from:
Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT.
Marketing Authorisation Holder: Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.