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EPAR summary for the public

Tresiba

insulin degludec

This is a summary of the European public assessment report (EPAR) for Tresiba. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Tresiba.

What is Tresiba?

Tresiba is a medicine that contains the active substance insulin degludec. It is available as a solution for injection in a cartridge (100 units/ml) and in a pre-filled pen (100 units/ml and 200 units/ml).

What is Tresiba used for?

Tresiba is used to treat type 1 and type 2 diabetes in adults and children aged 1 to 18 years of age.

The medicine can only be obtained with a prescription.

How is Tresiba used?

Tresiba is injected once a day, preferably at the same time every day. It is given as an injection under the skin in the thigh, upper arm or abdominal wall (at the front of the waist). The place within the chosen area should be changed with each injection to reduce the risk of lipodystrophy (changes in the distribution of body fat) under the skin that can affect the amount of insulin absorbed.

The correct dose is determined individually for each patient. In type 1 diabetes, Tresiba must always be used in combination with rapid acting insulin, which is injected at mealtimes. In type 2 diabetes, Tresiba can be used alone or in combination with diabetes medicines given by mouth, GLP-1 receptor agonist medicines and rapid acting mealtime insulin.

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How does Tresiba work?

Diabetes is a disease in which the body does not produce enough insulin to control the level of blood sugar or when the body is unable to use insulin effectively. Tresiba is a replacement insulin that is very similar to the natural insulin with a difference that it is absorbed more slowly in the body and takes longer to reach its target. This means that Tresiba has a long duration of action. Tresiba acts in the same way as naturally produced insulin and helps glucose enter cells from the blood. By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced.

How has Tresiba been studied?

Tresiba has been studied in three main studies involving 1,578 adults with type 1 diabetes, where Tresiba (in combination with rapid acting mealtime insulin) was compared with insulin glargine or insulin detemir (other long acting insulins).

Six other main studies involving 4,076 adults with type 2 diabetes compared Tresiba with insulin glargine, insulin detemir or sitagliptin (a medicine taken by mouth for type 2 diabetes). Patients in these studies could also be given other diabetes medicines or rapid-acting insulin at mealtimes if needed. Another main study involving 177 adults with type 2 diabetes investigated the effectiveness of combining Tresiba and liraglutide (a GLP-1 receptor agonist).

In addition Tresiba was compared with insulin detemir in one main study involving 350 children aged 1 to 18 years of age with type 1 diabetes. Patients were also given rapid-acting insulin at mealtimes. After 26 weeks of treatment, patients had the option to either stop treatment or continue with it for up to a year.

All of the studies measured the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which is the percentage of haemoglobin in the blood attached to glucose. HbA1c gives an indication of how well the blood glucose is controlled. Studies lasted for six months or one year.

What benefit has Tresiba shown during the studies?

The studies showed that Tresiba was at least as effective as other long acting insulins in controlling blood glucose levels in adults with type 1 and type 2 diabetes, and more effective than sitagliptin in adults with type 2 diabetes. Across the studies, the average reduction in HbA1c levels with Tresiba treatment was 0.6 percentage points in adults with type 1 diabetes and 1.2 points in adults with type 2 diabetes.

In children, the effects of Tresiba on blood glucose control were similar to those of insulin detemir. After 26 weeks of treatment with Tresiba, the average reduction in HbA1c was 0.2 percentage points (HbA1c decreased from 8.2% to 8.0%) compared with a reduction of 0.3 percentage points with insulin detemir (HbA1c decreased from 8.0% to 7.7%).

What is the risk associated with Tresiba?

The most frequently reported side effect during treatment with Tresiba (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose levels).

For the full list of side effects and restrictions with Tresiba, see the package leaflet.

Why has Tresiba been approved?

The CHMP concluded that Tresiba is effective in controlling blood glucose levels in patients with type 1 and type 2 diabetes. Regarding its safety, the Committee concluded that Tresiba is generally safe and its side effects are comparable to those of other insulin analogues with no unexpected side effects reported. It also noted that Tresiba reduces the risk of hypoglycaemia during the night in patients with type 1 and type 2 diabetes. The CHMP noted that the higher strength formulation of Tresiba met a medical need for patients requiring higher dose insulin (such as overweight patients), which would allow these patients to take their daily dose in a single injection rather than two injections. For adolescents with type 2 diabetes, the CHMP concluded that although safety and effectiveness had only been shown for type 1 diabetes, the results of studies carried out in adolescents with type 1 and other studies in adults with type 2 diabetes could be applied to adolescents with type 2. The CHMP decided that Tresiba's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Tresiba?

A risk management plan has been developed to ensure that Tresiba is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tresiba, including the appropriate precautions to be followed by healthcare professionals and patients.

The company that markets Tresiba will provide educational materials to healthcare professionals expected to treat or dispense medicines to patients with diabetes, aimed particularly at raising awareness of the higher strength formulation of Tresiba in order to ensure that the patient is prescribed the correct strength. It will also produce educational materials for patients on how to use Tresiba correctly, which they should receive through their doctor together with suitable training.

Other information about Tresiba

The European Commission granted a marketing authorisation valid throughout the European Union for Tresiba on 21 January 2013.

The full EPAR for Tresiba can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Tresiba, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2015.