20 March 2014
EMA/CHMP/164154/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Tresiba

Insulin degludec

On 20 March 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Tresiba. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication to include the combination of Tresiba with GLP-1 receptor agonists. This new indication is reflected in section 4.2 of the SmPC as follows:

"*Use of 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 followed by individual dosage adjustments.

When adding GLP-1 receptor agonists to Tresiba, it is recommended to reduce the dose of Tresiba by 20% to minimise the risk of hypoglycaemia. Subsequently, dosage should be adjusted individually."

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

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