



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Tresiba

insulin degludec

On 18 October 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tresiba, 100 units/ml and 200 units/ml, solution for injection, intended for the treatment of diabetes mellitus. The applicant for this medicinal product is Novo Nordisk A/S. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Tresiba is insulin degludec, a basal insulin. Insulin degludec binds specifically to the human insulin receptor and results in the same pharmacological effects as human insulin. The ATC code for Tresiba has not been assigned yet. Insulin degludec has been developed both as a 100 units/ml formulation and a 200 units/ml formulation in order to accommodate a wide range of insulin requirements.

The benefits with Tresiba are its ability to lower blood glucose levels and a lower risk of nocturnal hypoglycaemia when compared with insulin glargine. Despite positive effects on nocturnal hypoglycaemia overall hypoglycaemia remained the most common side effect.

A pharmacovigilance plan for Tresiba will be implemented as part of the marketing authorisation.

The approved indication is: "Treatment of diabetes mellitus in adults".

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

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Tresiba and therefore recommends the granting of the marketing authorisation.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

