24 July 2014
EMA/CHMP/424921/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xultophy

insulin degludec / liraglutide

On 24 July 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal Xultophy, 100 units/mL + 3.6 mg/mL, solution for injection, intended for the treatment of type 2 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 Xultophy is insulin degludec / liraglutide, a fixed dose combination of a basal insulin and a glucagon-like peptide 1 (GLP-1) receptor agonist. Insulin degludec binds specifically to the human insulin receptor and results in the same pharmacological effects as human insulin. Liraglutide acts via enhancing glucose-dependent insulin secretion and reducing glucagon release.

The benefits with Xultophy are its clinically relevant effect on glycaemic control in patients with type 2 diabetes when used in combination with other oral glucose-lowering medicinal products. Xultophy has a neutral effect on body weight. The most common side effects are hypoglycaemia and gastrointestinal adverse reactions such as nausea and diarrhoea.

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

The approved indication is: "Xultophy is indicated for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control in combination with oral glucose-lowering medicinal products when these alone or combined with basal insulin do not provide adequate glycaemic control (see sections 4.4 and 5.1 for available data on the different combinations)."

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.

[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.

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