10 November 2016
EMA/CHMP/715538/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Suliqua

insulin glargine / lixisenatide

On 10 November 2016 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Suliqua, intended for treatment of type 2 diabetes. The applicant for this medicinal product is Sanofi-aventis groupe.

Suliqua is a fixed-ratio combination of insulin glargine, a basal insulin analogue, and lixisenatide, a glucagon-like peptide 1 (GLP-1) receptor agonist. Insulin glargine binds specifically to the human insulin receptor and results in the same pharmacological effects as human insulin. Lixisenatide acts via enhancing glucose-dependent insulin secretion and reducing glucagon release. Suliqua will be available as a solution for injection (insulin 100 units/ml with lixisenatide 33 or 50 micrograms/ml).

The benefits with Suliqua are its clinically relevant effect on glycaemic control in patients with type 2 diabetes when used in combination with metformin. Suliqua has a neutral effect on body weight. The most common side effects are hypoglycaemia, dizziness and gastrointestinal adverse reactions such as nausea and diarrhoea.

The full indication is: "Suliqua is indicated in combination with metformin for the treatment of adults with type 2 diabetes mellitus to improve glycaemic control when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product or with basal insulin".

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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