30 January 2020
EMA/CHMP/41157/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Suliqua

insulin glargine / lixisenatide

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Suliqua. The marketing authorisation holder for this medicinal product is sanofi-aventis groupe.

The CHMP adopted a change to the existing indication as follows:[2]

> "Suliqua is indicated ~~in combination with metformin~~ for the treatment of adults with **insufficiently controlled** type 2 diabetes mellitus to improve glycaemic control ~~when this has not been provided by~~ **as an adjunct to diet and exercise in addition to** metformin ~~alone~~ **with or without** ~~or metformin combined with another oral glucose lowering medicinal product or with basal insulin~~(**SGLT-2 inhibitors. (For study results with respect to effect on glycaemic control, and the populations studied,** see section 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 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 a decision on this change 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 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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