EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2018
EMA/CHMP/250993/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xultophy

insulin degludec / liraglutide

On 26 April 2018, 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 Xultophy. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

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

> "Xultophy is indicated for the treatment of adults with **insufficiently controlled** type 2 diabetes mellitus to improve glycaemic control **as an adjunct to diet and exercise** ~~in combination with oral glucose-lowering medicinal products when these alone or combined with a GLP-1 receptor agonist or basal insulin do not provide adequate glycaemic control~~ **in addition to other oral medicinal products for the treatment of diabetes.** ~~(~~**For study results with respect to combinations, effects on glycaemic control, and the populations studied,** see sections 4.4**, 4.5** 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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