



22 June 2017  
EMA/CHMP/378657/2017  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Victoza liraglutide

On 22 June 2017, 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 Victoza. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

The CHMP adopted a change to the existing indication. The indication will read as follows<sup>2</sup>:

"Victoza is indicated for **the** treatment of adults with **insufficiently controlled** type 2 diabetes mellitus ~~to achieve glycaemic control as~~ **an adjunct to diet and exercise**:-

- ~~as Monotherapy When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of~~ **when** metformin is considered inappropriate due to intolerance or contraindications.

#### Combination therapy

~~In combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4 and 5.1 for available data on the different combinations):-~~

- **in addition to other medicinal products for the treatment of diabetes.**

**For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1."**

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.

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

<sup>2</sup> New text in bold, removed text as strikethrough

