14 December 2017
EMA/CHMP/726991/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ozempic

semaglutide

On 14 December 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ozempic, intended for the treatment of type 2 diabetes. The applicant for this medicinal product is Novo Nordisk A/S.

Ozempic will be available as a 1.34 mg/ml solution for injection. The active substance of Ozempic is semaglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist (ATC code: A10B). Like native GLP-1, semaglutide leads to an increase in glucose-dependent insulin secretion and a reduction in glucagon release.

The benefits with Ozempic are its clinically relevant effect on glycaemic control in patients with type 2 diabetes when used in combination with other glucose-lowering medicinal products or on its own when metformin cannot be used. Ozempic has also a beneficial effect on body weight. The most common side effects are hypoglycaemia when used in certain combinations and gastrointestinal side effects such as nausea and diarrhoea.

The full indication is:

"Ozempic is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- 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 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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