30 January 2020
EMA/43724/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rybelsus

semaglutide

On 30 January 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rybelsus, intended for the treatment of type 2 diabetes. The applicant for this medicinal product is Novo Nordisk A/S.

Rybelsus will be available as oral tablets (3 mg, 7 mg and 14 mg). The active substance of Rybelsus is semaglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist (ATC code: A10BJ06). Like native GLP-1, semaglutide leads to an increase in glucose-dependent insulin secretion and a reduction in glucagon release.

Semaglutide has already been authorised in the EU as Ozempic for subcutaneous use.

The benefits with Rybelsus are its ability to improve 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. Rybelsus has also a beneficial effect on body weight. The most common side effects are hypoglycaemia when used in combination with insulin or sulfonylurea, and gastrointestinal side effects such as nausea and diarrhoea.

The full indication is:

" Rybelsus 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

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

[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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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.