10 December 2020
EMA/CHMP/650408/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ogluo

glucagon

On 10 December 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 Ogluo, intended for the treatment of severe hypoglycaemia in diabetes mellitus. The applicant for this medicinal product is Xeris Pharmaceuticals Ireland Limited.

Ogluo will be available as 0.5 and 1 mg solution for injection. The active substance of Ogluo is glucagon, a pancreatic hormone (ATC code: H04AA01); glucagon increases blood glucose concentration by stimulating glycogen breakdown and release of glucose from the liver.

The benefits with Ogluo are its ability to restore blood glucose levels in hypoglycaemic subjects. The most common side effects are nausea and vomiting.

Ogluo is a hybrid medicine[2] of GlucaGen/GlucaGen Hypokit; GlucaGen has been authorised in the EU since October 1962. Ogluo contains the same active substance as GlucaGen but is available as a ready-to-use formulation intended for subcutaneous injection.

The full indication is:

> Ogluo is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 2 years and over with diabetes mellitus.

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
[2] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

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