17 October 2019
EMA/CHMP/542297/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Baqsimi

glucagon

On 17 October 2019 , the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Baqsimi, intended for the treatment of severe hypoglycaemia.

The applicant for this medicinal product is Eli Lilly Nederland B.V.

Baqsimi will be available as 3 mg nasal powder. The active substance of Baqsimi 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 Baqsimi are its ability to restore blood glucose levels in hypoglycaemic subjects. The most common side effects are watery eyes, upper respiratory tract irritation, nausea, headache and vomiting.

The full indication is: "Baqsimi is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 4 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

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