30 May 2024
EMA/222106/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zegalogue

dasiglucagon

On 30 May 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zegalogue, intended for the treatment of severe hypoglycaemia in patients with diabetes mellitus.

The applicant for this medicinal product is Zealand Pharma A/S.

Zegalogue will be available as 0.6 mg solution for injection. The active substance of Zegalogue is dasiglucagon, a glycogenolytic hormone that increases blood glucose concentration by activating hepatic glucagon receptors, stimulating glycogen breakdown and promoting the release of glucose from the liver.

In two studies in children from 6 years of age and adults with diabetes mellitus, treatment of insulin-induced hypoglycaemia with Zegalogue reduced the time required to increase plasma glucose compared with placebo, with a median time to recovery of 10 minutes. More patients experienced plasma glucose recovery with Zegalogue compared with placebo. The most common side effects with Zegalogue are nausea, vomiting and headache.

The full indication is:

> Zegalogue is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged 6 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union