24 July 2025
EMADOC-1700519818-2288212
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Baqsimi

glucagon

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Baqsimi. The marketing authorisation holder for this medicinal product is Amphastar France Pharmaceuticals.

The CHMP adopted an extension to an existing indication to include treatment of severe hypoglycaemia in children with diabetes mellitus from 1 year of age. The full indication for Baqsimi will therefore be as follows:[2]

> Baqsimi is indicated for the treatment of severe hypoglycaemia in adults, adolescents, and children aged **1 year** ~~4 years~~ and over with diabetes mellitus.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to 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] New text in bold, removed text as strikethrough

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