



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2026
EMA/CHMP/38012/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Bysumlog insulin lispro

On 26 February 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Bysumlog, intended for the treatment of diabetes mellitus.

The applicant for this medicinal product is Gan & Lee Pharmaceuticals Europe GmbH.

Bysumlog will be available as a 100 unit/ml solution for injection in a pre-filled pen. The active substance of Bysumlog is insulin lispro, a fast-acting insulin analogue (ATC code: A10AB04), which has a more rapid onset of action than human soluble insulin, thus allowing it to be given closer to a meal. Insulin lispro regulates glucose metabolism by facilitating glucose uptake from the blood through activating insulin receptors on muscle and fat cells, and by inhibiting glucose output from the liver.

Bysumlog is a biosimilar medicinal product. It is highly similar to the reference product Humalog (insulin lispro), which was authorised in the EU on 30 March 1996. Data show that Bysumlog has comparable quality, safety and efficacy to Humalog. More information on biosimilar medicines can be found [here](#).

The full indication is:

For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Bysumlog is also indicated for the initial stabilisation of diabetes mellitus.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website 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

