13 November 2025
EMA/337755/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ondibta

insulin glargine

On 13 November 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ondibta, intended for the treatment of diabetes mellitus.

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

Ondibta will be available as a 100 units/ml solution for injection. The active substance of Ondibta is insulin glargine, a long-acting insulin analogue (ATC code: A10AE04). Insulin glargine binds specifically to the human insulin receptor and results in the same pharmacological effects as human insulin.

Ondibta is a biosimilar medicinal product. It is highly similar to the reference product Lantus (insulin glargine), which was authorised in the EU on 9 June 2000. Data show that Ondibta has comparable quality, safety and efficacy to Lantus (insulin glargine).

More information on biosimilar medicines can be found here.

The full indication is:

> Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.

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

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