18 September 2025
EMA/CHMP/297654/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kyinsu

insulin icodec / semaglutide

On 18 September 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 Kyinsu, intended for treatment of type 2 diabetes mellitus.

The applicant for this medicinal product is Novo Nordisk A/S.

Kyinsu will be available as a 700 U/ml / 2 mg/ml solution for injection in pre-filled pens. The active substances of Kyinsu are insulin icodec and semaglutide, insulins and analogues for injection, long-acting (ATC code: A10AE57). Kyinsu combines two active substances with complementary mechanisms of action to improve glycaemic control: insulin icodec, a basal insulin analogue, and semaglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist. Insulin icodec regulates glucose metabolism by binding to insulin receptors. Semaglutide regulates insulin and glucagon secretion in a glucose-dependant manner by selectively binding to and activating the GLP-1 receptor, the target for native GLP-1.

The benefits of Kyinsu are its clinically relevant effect on glycaemic control in patients with type 2 diabetes inadequately controlled with daily basal insulin or GLP-1 receptor agonist, as shown in three multinational, multicentre, randomised, active-controlled, parallel-group phase 3 clinical studies. The most common side effects with Kyinsu include hypoglycaemia and gastrointestinal adverse reactions, including nausea and diarrhoea.

The full indication is:

> Kyinsu is indicated for the treatment of adults with type 2 diabetes mellitus insufficiently controlled on basal insulin or glucagon-like peptide 1 (GLP-1) receptor agonists as an adjunct to diet and exercise in addition to oral antidiabetic medicinal products.
> For study results with respect to combinations, effects on glycaemic control, and the populations studied, see sections 4.4, 4.5 and 5.1.

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

[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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languages after the marketing authorisation has been granted by the European Commission.