21 March 2024
EMA/CHMP/107168/2024
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Awiqli

## insulin icodec

On 21 March 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 Awiqli, intended for the treatment of diabetes mellitus. The applicant for this medicinal product is Novo Nordisk A/S.

Awiqli will be available as 700 U/ml solution for injection in pre-filled pen. The active substance of Awiqli is insulin icodec, a long-acting human insulin used in diabetes (ATC code: A10AE07). The primary action of insulin icodec is to regulate glucose metabolism.

Awiqli is a basal insulin given subcutaneously once a week. The efficacy of a once-weekly injection of insulin icodec was compared with basal insulin once-daily in six confirmatory randomised clinical studies. The results show that insulin icodec is non-inferior to once-daily basal insulin in lowering HbA1c levels.

The most common side effect with Awiqli is hypoglycaemia.

Insulin icodec will mainly be used in patients with type 2 diabetes, and should only be used in patients with type 1 diabetes for which a clear benefit of a once-weekly administration is expected. In patients with type 1 diabetes, hypoglycaemic events are more common compared to daily basal insulin.

The full indication is:

Treatment of diabetes mellitus in adults

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