25 June 2026
EMADOC-1829012207-54438
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Onswik

insulin efsitora alfa

On 25 June 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 Onswik, intended for the treatment of type 2 diabetes mellitus.

The applicant for this medicinal product is Eli Lilly Nederland B.V.

Onswik will be available as a 500 unit/ml and 1000 unit/ml solution for injection in a pre-filled pen. The active substance of Onswik is insulin efsitora alfa, a long-acting basal insulin analogue used in diabetes (ATC code: not yet assigned). The primary activity of insulin efsitora alfa is the regulation of glucose metabolism. Insulin and its analogues lower blood glucose by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin also inhibits lipolysis and proteolysis and enhances protein synthesis.

The benefit of Onswik is improved glycaemic control. The glucose-lowering effect was demonstrated in QWINT 1-4 phase 3 randomised, active-controlled clinical trials, in which once-weekly insulin efsitora alfa achieved reductions in glycosylated haemoglobin (HbA1c) comparable to those achieved with once-daily basal insulin. Observed differences in HbA1c versus comparators ranged from -0.01% to -0.09% in insulin-naïve and insulin-experienced populations. The most common side effect with Onswik is hypoglycaemia.

The full indication is treatment of type 2 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 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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