29 January 2026
EMA/CHMP/17332/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kayshild

semaglutide

On 29 January 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Kayshild, intended for the treatment of adults with non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH). The applicant for this medicinal product is Novo Nordisk A/S.

Kayshild will be available as a 0.25 mg, 0.5 mg, 1 mg, 1.7 mg and 2.4 mg solution for injection in pre-filled pens. The active substance of Kayshild is semaglutide, a glucagon-like peptide-1 (GLP-1) analogue (ATC code: A10BJ06). Semaglutide is a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor. The GLP-1 receptor is not expressed in the liver, and the liver-specific mechanism of action is mediated through improvement in metabolic factors, including weight loss, improved glucose and lipid metabolism, and reduced inflammation. Moreover, semaglutide reduces liver fat deposition.

The benefits of Kayshild are the resolution of MASH with no worsening of liver fibrosis as well as an improvement in fibrosis with no worsening of MASH compared with placebo, as observed in a multicentre, randomised, double-blind, placebo-controlled clinical trial in adults with MASH and moderate to advanced liver fibrosis. The most common side effects with Kayshild are gastrointestinal disorders, including nausea, diarrhoea, constipation and vomiting, and fatigue.

The full indication is:

> Kayshild is indicated in conjunction with diet and exercise for the treatment of adults with non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (fibrosis stages F2 to F3).

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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.

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