17 September 2026
EMADOC-1829012207-71085
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zeydovio

glepaglutide

On 17 September 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 Zeydovio, intended for the treatment of short bowel syndrome.

The applicant for this medicinal product is Zealand Pharma A/S.

Zeydovio will be available as a 10 mg solution for injection in a pre-filled pen. The active substance of Zeydovio is glepaglutide, an alimentary tract and metabolism product (ATC code: A16AX26). Glepaglutide is a long-acting analogue of GLP-2, a peptide that has intestinotrophic properties It increases intestinal and portal blood flow and inhibits gastric acid secretion and intestinal motility. Glepaglutide promotes normal growth of the intestinal mucosa, with increased mucosal thickness, intestinal epithelial height and crypt depth.

The benefits of Zeydovio are its ability to reduce patients' need for parenteral support, as shown by a greater reduction in weekly parenteral support volume with glepaglutide given twice weekly for 24 weeks compared with placebo. The most common side effects are injection site reactions, gastrointestinal stoma complications (for patients with a stoma), abdominal pain, abdominal extension, nausea, fluid retention/fluid overload and vomiting.

The full indication is:

> Zeydovio is indicated for the treatment of adults with Short Bowel Syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery.

Treatment should be initiated under the supervision of a medical professional with experience in the treatment of SBS.

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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