13 November 2025
EMA/358510/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Teduglutide Viatris

teduglutide

On 13 November 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 Teduglutide Viatris, intended for the treatment of people with short bowel syndrome.

The applicant for this medicinal product is Viatris Limited.

Teduglutide Viatris will be available as a 5 mg powder and solvent for solution for injection. The active substance of Teduglutide Viatris is teduglutide, an alimentary tract and metabolism product (ATC code: A16AX08). Teduglutide is an analogue of glucagon-like peptide-2 (GLP-2). The naturally occurring human GLP-2 is a peptide secreted by L cells in the intestine which increases intestinal and portal blood flow, inhibit gastric acid secretion, and decrease intestinal motility. In several non-clinical studies, teduglutide has been shown to preserve mucosal integrity by promoting repair and normal growth of the intestine through an increase in villus height and crypt depth.

Teduglutide Viatris is a generic of Revestive, which has been authorised in the EU since 30 August 2012. Studies have demonstrated the satisfactory quality of Teduglutide Viatris to the reference product Revestive. Since Teduglutide Viatris is administered subcutaneously and is 100% bioavailable, a bioequivalence study versus the reference product Revestive was not required. A question and answer document on generic medicines can be found here.

The full indication is:

> Teduglutide Viatris is indicated for the treatment of patients 4 months corrected gestational age and above with Short Bowel Syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery.

Treatment with Teduglutide Viatris should be initiated under the supervision of a medical professional experienced in the treatment of short bowel syndrome.

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.