



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2026
EMADOC-1829012207-51237
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Liraglutide Stada

liraglutide

On 21 May 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 Liraglutide Stada, intended for the treatment of insufficiently controlled type 2 diabetes.

The applicant for this medicinal product is STADA Arzneimittel AG.

Liraglutide Stada will be available as a 6 mg/ml solution for injection in pre-filled pen. The active substance of Liraglutide STADA is liraglutide, a glucagon-like peptide-1 (GLP-1) analogue (ATC code: A10BJ02). Liraglutide binds to and activates the GLP-1 receptor. Liraglutide acts in the same way as incretin hormones produced in the gut. It increases the amount of insulin released by the pancreas in response to food, helping to control blood glucose levels.

Liraglutide Stada is a hybrid medicine² of Victoza (liraglutide), which has been authorised in the EU since 30 June 2009. Liraglutide STADA contains the same active substance as Victoza, but it is chemically synthesised, whereas the active substance in the reference products is of biological origin.

Studies have demonstrated the satisfactory quality of Liraglutide Stada, and its bioequivalence to the reference product Victoza (liraglutide).

The full indication is:

Liraglutide STADA is indicated for the treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes

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 Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.



For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1.

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.