21 May 2026
EMADOC-1829012207-51236
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ablymico

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 Ablymico, indicated for weight management as an adjunct to a reduced-calorie diet and increased physical activity.

The applicant for this medicinal product is STADA Arzneimittel AG.

Ablymico will be available as a 6 mg/ml solution for injection in pre-filled pen. The active substance of Ablymico is liraglutide, a glucagon-like peptide-1 (GLP-1) analogue (ATC code: A10BJ02). Liraglutide binds to and activates the GLP-1 receptor. GLP-1 is a physiological regulator of appetite and food intake. Liraglutide regulates appetite by increasing feeling of fulness, while reducing feeling of hunger and craving, leading to lower energy intake.

Ablymico is a hybrid medicine[2] of Saxenda (liraglutide), which has been authorised in the EU since 23 March 2015. Ablymico contains the same active substance as Saxenda, but it is chemically synthesised, whereas the active substance in the reference products is of biological origin.

Studies have demonstrated the satisfactory quality of Ablymico, and its bioequivalence to the reference product Saxenda (liraglutide).

The full indication is:

> Adults
>
> Ablymico is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial Body Mass Index (BMI) of:
>
> - ≥ 30 kg/m^2 (obesity), or

[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.

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- ≥ 27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

Treatment with Ablymico should be discontinued after 12 weeks on the 3.0 mg/day dose if patients have not lost at least 5 % of their initial body weight.

Adolescents (≥ 12 years)

Ablymico can be used as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescent patients from the age of 12 years and above with:

- obesity (BMI corresponding to ≥ 30 kg/m^2 for adults by international cut-off points)* and
- body weight above 60 kg.

Treatment with Ablymico should be discontinued and re-evaluated if patients have not lost at least 4 % of their BMI or BMI z score after 12 weeks on the 3.0 mg/day or maximum tolerated dose.

*IOTF BMI cut-off points for obesity by sex between 12-18 years (see table 1), in accordance with study design of the Trial 4180, see section 5.1.

[Table 1, which provide BMI cut off points for obesity by sex and age in adolescents aged 12 years and older will be included in section 4.1 of the summary of product characteristics.]

Children (6 to < 12 years)

Ablymico is indicated as an adjunct to healthy nutrition and increased physical activity for weight management in children from the age of 6 to < 12 years with

- obesity (BMI ≥ 95th percentile)* and
- body weight ≥ 45 kg

Treatment with Ablymico should be discontinued and re-evaluated if patients have not lost at least 4 % of their BMI or BMI z score after 12 weeks on the 3.0 mg/day or maximum tolerated dose.

*CDC BMI cut-off points for obesity (≥ 95th percentile) by sex between 6 to < 12 years (see table 2), in accordance with study design of the Trial 4392, see section 5.1.

[Table 2, which provide BMI cut-off points for obesity by sex and age in children ages 6 to less than 12 years of age will be included in section 4.1 of the SmPC.]

Detailed recommendations for the use of this product will be described in the 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.