22 May 2025
EMA/158218/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Saxenda

liraglutide

On 22 May 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Saxenda. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

The CHMP adopted an extension to the existing indication to include treatment of children aged 6 to less than 12 years, as follows:

Children (6 to <12 years)

Saxenda 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 Saxenda 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.

For information, the full indications for Saxenda will be as follows:[2]

Adults

Saxenda 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/m² (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] New text in bold

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- ≥ 27 kg/m² to <30 kg/m² (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 Saxenda 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)

Saxenda 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 Saxenda 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.**

Children (6 to <12 years)

Saxenda 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 Saxenda 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.**

Tables 1 and 2 which provide BMI cut-off points for obesity by sex and age in children and adolescents, are included in section 4.1 of the summary of product characteristics (SmPC).

Detailed recommendations for the use of this product will be described in the updated SmPC, which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.