25 June 2026
EMADOC-1700519818-3024086
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Orladeyo

berotralstat

On 25 June 2026, 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 Orladeyo. The marketing authorisation holder for this medicinal product is BioCryst Ireland Limited.

The CHMP adopted a new pharmaceutical form, film-coated granules in sachet, in 72 mg, 96 mg, 108 mg and 132 mg strengths, associated with an extension to the existing indication to include children from 2 years of age weighing at least 15 kg, as follows:

> Orladeyo is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in:
>
> - children aged 2 to less than 12 years weighing at least 15 kg
> - adolescents aged 12 and older weighing less than 40 kg

The CHMP also adopted a change to the indication for the already authorised 150 mg hard capsules to add a minimum weight requirement, as follows:[2]

> Orladeyo is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older **weighing at least 40 kg**.

This minimum weight requirement had previously been stated only in section 4.2 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 in the revised European public assessment report (EPAR), and will be available 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.

[1] Summary 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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