



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 October 2024
EMA/CHMP/477910/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Cerdelga eliglustat

On 17 October 2024, 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 Cerdelga. The marketing authorisation holder for this medicinal product is Sanofi B.V.

The CHMP adopted a new strength, 21 mg hard capsules, along with an extension to the existing indication to include treatment of children from 6 years of age weighing at least 15 kg, as follows:

Paediatric population (from 6 to < 18 years of age) weighing ≥ 15 kg

Cerdelga is indicated for paediatric patients with GD1 who are 6 years and older with a minimum body weight of 15 kg, who are stable on enzyme replacement therapy (ERT), and who are CYP2D6 PMs, IMs or EMs.

For information, the full indications will be as follows:²

Adults

Cerdelga is indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1), who are CYP2D6 poor metabolisers (PMs), intermediate metabolisers (IMs) or extensive metabolisers (EMs).

Paediatric population (from 6 to < 18 years of age) weighing ≥ 15 kg

Cerdelga is indicated for paediatric patients with GD1 who are 6 years and older with a minimum body weight of 15 kg, who are stable on enzyme replacement therapy (ERT), and who are CYP2D6 PMs, IMs or EMs.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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

