This material fulfils the conditions of the eliglustat marketing authorisation and has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

Please report suspected side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard or the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm. By reporting side effects, you can help provide more information on the safety of this medicine. Side effects can also be reported to Sanofi: Tel: 0800 090 2314. email: uk-drugsafety@sanofi.com.

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DATE OF MHRA APPROVAL: APRIL 2025

sanofi

Treating doctor's phone number: _____

Treating doctor's name: _____

Centre name: _____

Date eliglustat first prescribed: _____

CYP2D6 metaboliser type: _____

Patient's name: _____

CERDELGA▼ (eliglustat) PATIENT CARD

Information for the patient / caregivers

Please carry this card with you at all times and show it to any healthcare professional in order to inform them about your current treatment with eliglustat.

- Do not start any new prescription medication, over-the-counter medication, or herbal products without telling your / your child's doctor or pharmacist.
- Do not consume grapefruit products.

For more information on eliglustat, please refer to the Patient Information Leaflet (PIL)

Eliglustat 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). Eliglustat is also indicated for paediatric patients with GD1 who are 6 years and older with a minimum body weight of 25 kg, who are stable on enzyme replacement therapy (ERT), and who are CYP2D6 PMs, IMs or EMs.

For additional information, please refer to the Summary of Product Characteristics (SmPC)

Extensive Metaboliser (EM) and Intermediate Metaboliser (IM) patients:

- Eliglustat must not be used in combination with a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor
- Eliglustat must not be used in EM patients
  - with severe hepatic impairment
  - with mild or moderate hepatic impairment being treated with a strong or moderate CYP2D6 inhibitor

- Eliglustat is not recommended to be used
  - in EM patients with moderate hepatic impairment
  - in IM patients with any degree of hepatic impairment
- Eliglustat is not recommended to be used in combination with a strong CYP3A inducer
- Eliglustat should be used with caution in combination with:
  - a moderate CYP2D6 inhibitor
  - a strong or moderate CYP3A inhibitor
  - a P-gp or a CYP2D6 substrate (lower doses of such drugs may be required)
- Eliglustat is not recommended in EM or IM patients with end stage renal disease or in IM patients with mild, moderate or severe renal impairment
- Eliglustat dose should be reduced to ONCE a day dose:
  - in EM or IM patients concomitantly treated with a strong CYP2D6 inhibitor
  - in EM patients with mild hepatic impairment treated with a weak CYP2D6 inhibitor or any CYP3A inhibitor

Poor Metaboliser (PM) patients:

- Eliglustat must not be used in PM patients in combination with a strong CYP3A inhibitor
- Eliglustat is not recommended to be used in PM patients with any degree of hepatic impairment
- Eliglustat is not recommended to be used in PM patients in combination with:
  - a strong CYP3A inducer
  - a moderate CYP3A inhibitor
- Eliglustat is not recommended in PM patients with end stage renal disease or in PM patients with mild, moderate or severe renal impairment
- Eliglustat should be used with caution in PM patients in combination with:
  - a weak CYP3A inhibitor
  - a P-gp or a CYP2D6 substrate (lower doses of such drugs may be required)