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

If you notice any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet. You can also report side effects directly to: HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2, Tel: 01 6764971, Fax: 01 6762517, Website: www.hpra.ie, email: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Sanofi: IE: Tel: 01 403 5600. Email: IEPharmacovigilance@sanofi.com

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SANOFI GENZYME

Treating doctor's phone number: _____

Treating doctor's name: _____

Centre name: _____

Date Cerdelga® first prescribed: _____

CYP2D6 metaboliser type: _____

Patient's name: _____

CERDELGA (eliglustat) ▼
PATIENT ALERT CARD

Information for the patient

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 Cerdelga®

- Do not start any new prescription medication, over-the-counter medication, and herbal products without telling your doctor or pharmacist
- Do not consume grapefruit products

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

- Cerdelga should not be used concomitantly with medicines that may have an impact on liver enzymes that play a role in the metabolism of Cerdelga. In addition, patient's hepatic or renal status may have an impact on the metabolism of Cerdelga.
- Using Cerdelga together with such products or in patients with hepatic or renal impairment may either make Cerdelga less effective, or it may increase the eliglustat levels in the patient's blood.
- For detailed information on drug interactions with Cerdelga and use in patients with renal or hepatic impairment, please refer to the Summary of Product Characteristics available at www.hpra.ie or www.medicines.ie

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

- Cerdelga® must not be used in combination with a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor
- Cerdelga® 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
- Cerdelga® is not recommended to be used
  - in EM patients with moderate hepatic impairment
  - in IM patients with any degree of hepatic impairment
- Cerdelga® is not recommended to be used in combination with a strong CYP3A inducer
- Cerdelga® 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)
- Cerdelga® is not recommended in EM or IM patients with end stage renal disease or in IM patients with mild, moderate or severe renal impairment
- Cerdelga® dose should be reduced to 84 mg ONCE a day:
  - 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:

- Cerdelga® must not be used in PM patients in combination with a strong CYP3A inhibitor
- Cerdelga® is not recommended to be used in PM patients with any degree of hepatic impairment
- Cerdelga® is not recommended to be used in PM patients in combination with:
  - a strong CYP3A inducer
  - a moderate CYP3A inhibitor
- Cerdelga® is not recommended in PM patients with end stage renal disease or in PM patients with mild, moderate or severe renal impairment
- Cerdelga® 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)