PATIENT ALERT CARD

Important Risk Minimization Information for
Healthcare Professionals about Cerdelga (eliglustat)

Version 1 - Approved by SFDA December 2021

SANOFI GENZYME

PATIENT ALERT CARD

Patient's name: _____

Date CERDELGA first prescribed: _____

CYP2D6 metaboliser status: _____

Centre name: _____

Treating doctor's name: _____

Treating doctor's phone number: _____

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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 Eliglustat

- 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

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▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get to:

The National Pharmacovigilance Center (NPC)
Fax: +966-11-205-7662
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/

For SANOFI Pharmacovigilance, please contact:
Phone: +966-544-284-797
E-mail: Ksa_pharmacovigilance@sanofi.com

For Medical Information, Please contact: +966-12-669-3318, ksa.medicalinformation@sanofi.com

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Information for healthcare professionals

Eliglustat 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).

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

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Information for healthcare professionals

- Eliglustat 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:

- Eliglustat must not be used 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 combination with:
  - a strong CYP3A inducer
  - a moderate CYP3A inhibitor
- Eliglustatis 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 combination with:
  - a weak CYP3A inhibitor
  - a P-gp or a CYP2D6 substrate (lower doses of such drugs may be required)

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