CERDELGA®▼ (eliglustat)
GUIDE FOR PRESCRIBER

This material fulfils the conditions of the marketing authorisation and has been approved by the Health Products Regulatory Authority (HPRA).

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About this Guide

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 15 kg, who are stable on enzyme replacement therapy (ERT), and who are CYP2D6 PMs, IMs or EMs. It is not intended to be used in patients with Gaucher disease type 2 (GD2) or type 3 (GD3).

This guide has been developed as part of the eliglustat educational programme and is intended for physicians who initiate and supervise eliglustat treatment. It is intended to improve the use of eliglustat by positively influencing appropriate actions.

It contains:

1. Information on CYP2D6 genotyping assessment
2. Checklist of actions to be completed before and after treatment initiation
3. Information on reporting suspected adverse drug reactions

In addition, a *Patient Card* has been developed that you should give to patients / caregivers initiating eliglustat treatment. If needed, cards are available upon request from Sanofi Medical Information: Tel: 01 403 5600, E-mail: IEmedinfo@sanofi.com.

This card is a liaison tool to inform any healthcare professionals who are treating patients receiving eliglustat about drug-drug interactions that should be considered before prescription or delivery of any additional medicinal products, including herbal products. The patient (or caregivers when appropriate) should be told to carry and show this card to any healthcare professional who may be prescribing or delivering additional medicinal products. Moreover, it contains information to remind the patient / caregivers about the risk of self-medication and consumption of grapefruit products.

For more information on eliglustat, please refer to Summary of Product Characteristics (SmPC) which is available on www.medicines.ie.

Predicted Cytochrome P450 2D6 Metabolic Activity

Eliglustat is to be used only in patients who have a predicted CYP2D6 poor, intermediate or extensive metaboliser phenotype based on genotyping. Determination of the patient's CYP2D6 phenotype prior to starting eliglustat is required.

Genotyping to determine the patient's CYP2D6 phenotype is to be performed using an established genetic laboratory test that is able to detect a specific set of CYP2D6 alleles with adequate accuracy, sensitivity and specificity in order to ensure consistent identification of CYP2D6 metaboliser status.

To get more information about testing you can contact Sanofi at: Tel: 01 4035 600, E-mail: IEmedinfo@sanofi.com

Prescriber Check List

1. Before treatment initiation, it should be verified if the patient is appropriate for eliglustat treatment.

Three steps must be achieved to confirm patient's eligibility for eliglustat treatment initiation:

STEP 1	Patient must be an adult with Gaucher disease type 1 (GD1) or paediatric patient (from 6 to <18 years of age) with GD1, with a minimum body weight of 15 kg, who are stable on enzyme replacement therapy (ERT) and who can swallow an intact capsule.
STEP 2	Patient must be a CYP2D6 poor (PM), intermediate (IM) or extensive metaboliser (EM)

STEP 3

Standard dosing schedule according to patient's CYP2D6 phenotype

CYP2D6 phenotype		Extensive Metaboliser (EM)	Intermediate Metaboliser (IM)	Poor Metaboliser (PM)
Standard dosing for adults		84 mg Twice daily dose	84 mg Twice daily dose	84 mg Once daily dose
Standard dosing for children aged 6 years to <18 years with body weight of:	**≥50 kg**	84 mg twice daily	84 mg twice daily	84 mg once daily
	25 to <50 kg	84 mg twice daily	84 mg twice daily	42 mg once daily
	15 to <25 kg	42 mg twice daily	42 mg twice daily	21 mg once daily

Depending on the patient's CYP2D6 phenotype defined at step 2, the following situations are to be taken into account, based on concomitant medication use, as well as hepatic and renal status. For recommended adult and paediatric dosage strengths, see standard dosing schedule above. For additional information, please refer to the SmPC:

Concomitant use of CYP2D6 and/or CYP3A inhibitors increase plasma concentrations of eliglustat. This may cause mild increases in the PR, QRS, and QTc intervals.			
Strong or moderate CYP2D6 inhibitors + strong or moderate CYP3A inhibitors	**contraindicated**	**contraindicated**	see below for strong or moderate CYP3A inhibitors
Strong CYP2D6 inhibitors	Once daily dose	Once daily dose	Once daily dose
Moderate CYP2D6 inhibitors	Twice daily dose **with caution**	Twice daily dose **with caution**	Once daily dose
Strong CYP3A inhibitors	Twice daily dose **with caution**	Twice daily dose **with caution**	**contraindicated**
Moderate CYP3A inhibitors	Twice daily dose **with caution**	Twice daily dose **with caution**	**not recommended**
Weak CYP3A inhibitors	Twice daily dose	Twice daily dose	Once daily dose **with caution**
Grapefruit products fall under the category of strong CYP3A inhibitors and can increase plasma concentrations of eliglustat. Consumption of grapefruit or its juice should be avoided.			
Concomitant use of strong CYP3A inducers decrease plasma concentrations of eliglustat:			
Strong CYP3A inducers	**not recommended**	**not recommended**	**not recommended**
Concomitant use of agents whose exposure may be increased by eliglustat:			
P-gp substrates	Lower doses of substances which are P-gp substrates may be required		
CYP2D6 substrates	Lower doses of medicinal products that are CYP2D6 substrates may be required		
Patients with hepatic impairment	**EM**	**IM**	**PM**
Mild hepatic impairment	Twice daily dose	**not recommended**	**not recommended**
Mild hepatic impairment AND use of weak CYP2D6 inhibitor OR any CYP3A inhibitor	Once daily dose	**not recommended**	**not recommended**
Mild hepatic impairment AND use of strong or moderate CYP2D6 inhibitor	**contraindicated**	**not recommended**	**not recommended**
Moderate hepatic impairment	**not recommended**	**not recommended**	**not recommended**
Moderate hepatic impairment AND use of strong or moderate CYP2D6 inhibitor	**contraindicated**	**not recommended**	**not recommended**
Severe hepatic impairment	**contraindicated**	**not recommended**	**not recommended**
Patients with renal impairment	**EM**	**IM**	**PM**
Mild, moderate or severe renal impairment	Twice daily dose	**not recommended**	**not recommended**
End stage renal disease (ESRD)	**not recommended**	**not recommended**	**not recommended**

2. Patient Education

☐ You have informed the patient / caregivers about the drug-drug interactions that could occur with eliglustat and the importance of informing all healthcare professionals about the patient's current medications and treatment.

☐ You have instructed the patient / caregivers about the risk of self-medication and consumption of grapefruit products.

☐ You have provided the *Patient Card* to the patient / caregivers and instructed them about its use (i.e., you have discussed with them the importance of showing the card to all their healthcare professionals).

AT PATIENT FOLLOW-UP, CHECK THE FOLLOWING

3. Medical conditions

☐ Inquire about any changes in medical history or new medications since last visit (including over the counter medication or herbal products) and use of grapefruit products.

☐ Check for suspected adverse drug reactions.

4. Patient / caregivers education

☐ Check for appropriate use of the *Patient Card.*

☐ Remind patient / caregiver about the risk of self-medication and consumption of grapefruit products.

Reporting of Suspected Adverse Drug Reactions

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

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions by contacting HPRA Pharmacovigilance, website: www.hpra.ie

Adverse drug reactions can also be reported to Sanofi:
Tel: 01 403 5600. Email: IEPharmacovigilance@sanofi.com