CERDELGA®▼ (eliglustat)
GUIDE FOR PRESCRIBER

MAT-GB-2002125(v1.0) | DATE OF PREPARATION: SEPTEMBER 2020

About this Guide

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).

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

It contains:

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

In addition, a *Patient Alert Card* has been developed that you should give to patients initiating Cerdelga® treatment. If needed, cards are available upon request from Sanofi Medical Information: Tel: 0800 035 2525, E-mail: UK-medicalinformation@sanofi.com. This card is a liaison tool to inform any healthcare professionals who are treating patients receiving Cerdelga® about drug-drug interactions that should be considered before prescription or delivery of any additional medicinal products, including herbal products. The patient (or care givers when appropriate) should be told to carry and show this card at all times to any healthcare professional who may be prescribing or delivering additional medicinal products. Moreover, it contains information to remind the patient about the risk of self-medication and consumption of grapefruit products. An example of this card is attached in **Annex 1.**

For more information on Cerdelga®, please refer to Summary of Product Characteristics which is available on the Electronic Medicines Compendium (eMC) website www.medicines.org.uk/emc or contact Sanofi at: Tel: 0800 035 2525. E-mail:UK-medicalinformation@sanofi.com.

Annexes to the Guide:

- **Annex 1** : Patient Alert Card

Prescriber Check List

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

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

STEP 1	Patient must be an adult with Gaucher disease type 1
STEP 2	Patient must be a CYP2D6 poor (PM), intermediate (IM) or extensive metaboliser (EM)

STEP 3

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 additional information, please refer to the Summary of Product Characteristics:

CYP2D6 phenotype	Extensive Metaboliser (EM)	Intermediate Metaboliser (IM)	Poor Metaboliser (PM)
Standard dosing	84 mg twice daily (BID)	84 mg BID	84 mg once daily
Concomitant use of CYP2D6 and/or CYP3A inhibitors increase plasma concentrations of eliglustat:			
Strong or moderate CYP2D6 inhibitors + strong or moderate CYP3A inhibitors	**contraindicated**	**contraindicated**	see below for strong or moderate CYP3A inhibitors
Strong CYP2D6 inhibitors	84 mg once daily	84 mg once daily	84 mg once daily
Moderate CYP2D6 inhibitors	84 mg BID **with caution**	84 mg BID **with caution**	84 mg once daily
Strong CYP3A inhibitors	84 mg BID **with caution**	84 mg BID **with caution**	**contraindicated**
Moderate CYP3A inhibitors	84 mg BID **with caution**	84 mg BID **with caution**	**not recommended**
Weak CYP3A inhibitors	84 mg BID	84 mg BID	84 mg once daily **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			
Mild hepatic impairment	84 mg BID	**not recommended**	**not recommended**
Mild hepatic impairment AND use of weak CYP2D6 inhibitor OR any CYP3A inhibitor	84 mg once daily	**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			
Mild, moderate or severe renal impairment	84 mg BID	**not recommended**	**not recommended**
End stage renal disease (ESRD)	**not recommended**	**not recommended**	**not recommended**

2. Patient Education

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

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

☐ You have provided the *Patient Alert Card* to the patient/and instructed him/her 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 reactions

4. Patient education

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

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

Predicted Cytochrome P450 2D6 Metabolic Activity

Cerdelga® 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 Cerdelga® 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.

Sanofi Genzyme offer CYP2D6 metaboliser status testing free of charge in the UK. Alternatively, several suitable commercial tests are available.

To get more information about testing or accredited laboratories, you can contact Sanofi at:
Tel: 0800 035 2525, E-mail:UK-medicalinformation@sanofi.com

▼Reporting of Suspected Adverse Reactions

Cerdelga® 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 via the Yellow Card Scheme at yellowcard.mhra.gov.uk.

Suspected adverse reactions should also be reported to Sanofi:
Tel: 0800 090 2314. Email: UK-drugsafety@sanofi.com

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