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GUIDE FOR PRESCRIBER

SANOFI GENZYME

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Guide for Prescriber

CERDELGA is indicated for the long-term treatment of adult patients with Gaucher disease type 1.

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 Genzyme Medical Information 09-7666640. 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.

For more information on CERDELGA, please refer to Summary of Product Characteristics or contact Sanofi Genzyme at: 09-7666640.

1 Prescriber Check List

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

The appropriate patient for CERDELGA treatment is:

- ☐ An adult patient with Gaucher disease type 1
- ☐ A CYP2D6 poor (PM), intermediate (IM) or extensive metaboliser (EM)
- ☐ An IM or EM patient not being treated with a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor
  - CERDELGA dose for IM and EM patients is 84 mg twice a day
- ☐ A PM patient not being treated with a strong CYP3A inhibitor
  - CERDELGA dose for PM patients is 84 mg once a day

ALL BOXES SHOULD BE CHECKED AND CONFIRMED BEFORE INITIATING CERDELGA

2. Carefully consider use of CERDELGA, and refer to the Summary of Product Characteristics, for the following situations:

- ☐ Situations where the use of CERDELGA is **not recommended**
  - A PM patient being treated with a moderate CYP3A inhibitor
  - A PM, IM or EM patient being treated with a strong CYP3A inducer
- ☐ Situations where CERDELGA should be **used with caution**
  - An IM or EM patient being treated with a moderate CYP2D6 inhibitor
  - An IM or EM patient being treated with a strong or moderate CYP3A inhibitor
  - A PM patient being treated with a weak CYP3A inhibitor
- ☐ Other situations to consider
  - An IM or EM patient being treated with a strong CYP2D6 inhibitor
    - CERDELGA dosing regimen should be reduced to 84 mg ONCE a day
  - The patient is being treated with a P-gp or CYP2D6 substrate: lowering the dose of these medications may be required

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3. 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

4. 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

5. Patient education

- ☐ Check for appropriate use of the *Patient Alert Card*
- ☐ Remind patient about the risk of self-medication and consumption of grapefruit products

2 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. Several suitable commercials tests are available.

To get more information about accredited laboratories, you can contact Sanofi Genzyme at 09-7666640.

3 Reporting of Suspected Adverse Reactions

Reporting any suspected adverse reactions is important for the continued monitoring of the benefit/risk balance of all medicinal products. To report SUSPECTED ADVERSE REACTIONS, contact sanofi at **pv.genzyme@sanofi.com** Alternatively, suspected adverse event should be reported to the Ministry of Health by the online form for reporting adverse reactions located on the homepage of the Ministry of Health's website - **www.health.gov.il**.
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il

This Brochure format and content has been checked and approved by the Ministry of Health in April 2017

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