Unsolicited Individual Safety Information (ISI) Report Form

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

Version 1 - Approved by SFDA December 2021

SANOFI GENZYME

Unsolicited Individual Safety Information (ISI) Report Form

Grey fields are for Sanofi use only

1 ADMINISTRATIVE SECTION FOR AFFILIATE/PARTNER ONLY

Company contact date: / / Local PV receipt date: / /

Country of Occurrence:

Social Media case: Yes ☐ No ☐ If Yes: Name of the social media:

☐ INITIAL ☐ FOLLOW-UP Global Safety Database ID:

Local Reference ID: Local PTC ID: Global PTC ID:

2 PATIENT

Title, Name (first, middle, last)/Initials: ..... Gender: F ☐ M ☐ Unk ☐

Address, city, postal code, state:

Country: Phone:

Email address:

Date of Birth (DD/MM/YYYY): / / . Age or Age Group (at time of the reaction): .....

Height: cm/feet & inches Weight: kg/lb Registry ID #: Click here to enter text.

3 REPORTER

First Name: Last Name:

Occupation: .....

Address:

3 REPORTER

Zip / Postal Code:

Country:

Phone:

Fax:

E-mail address:

If the primary reporter is a consumer, is contact information provided for a HealthCare Professional? *Yes ☐ No ☐ NA ☐

If your country requires patient consent to contact the HCP, has the patient given their consent? *Yes ☐ **No ☐ NA ☐

*If YES, attempts should be made to contact the HCP **If NO, do not contact the HCP and document the exchange

Was FU request sent to reporter? Yes ☐ No ☐ NA ☐

The reporter will not have any further information ☐

The reporter does not wish to be contacted by the Pharmacovigilance Department ☐

SUSPECT MEDICATION / MEDICAL DEVICE (MD) / VACCINE (V)

Brand Name /INN	Indication	Dosage/ Unit/ Frequency/ Amount	Batch Number (Mandatory. If not available, enter NA/ if not obtainable at all enter NO)	Start Date (DD/MM /YYYY)	Stop Date or duration (DD/MM/YYYY)	Route of Administration	Company product (Yes/No)	Primary/Booster (V)	Site of Injection (V)	Side (V)
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Is medical device available for evaluation (MD)? ☐Yes ☐No
Did the problem occur with initial use or during re-use of the medical device (MD)? ☐Yes ☐No

For company suspect product inappropriately used as per local Marketing Authorization:
Is it intentional? ☐Yes ☐No ☐Unk *at the initiative of* ☐HCP ☐Consumer ☐Unk *for a therapeutic purpose?* ☐Yes ☐No ☐Unk

Comments (Complementary information: presentation, syringe, single dose, multidose, storage conditions):

5 CONCOMITANT MEDICATION / MEDICAL DEVICE / VACCINE

Brand Name /INN	Indication	Dosage/ Unit/ Frequency/ Amount	Batch Number	Start Date (DD/MM/ YYYY)	Stop Date or duration (DD/MM/ YYYY)	Route of Administration	Company product (Yes/No)	Primary/ Booster (V)	Site of Injection (V)	Side (V)
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Comments (Complementary information: presentation, syringe, single dose, multidose, storage conditions):

6 REACTION DESCRIPTION

Reaction	Date of Onset (DD/MM/YYYY)	Stop Date or Duration (DD/MM/YYYY)	Outcome	Corrective Treatment	Action Taken	Did reaction abate after product was stopped?	Did reaction recur after product was started again?	Kind of Reaction (V)	Lack of efficacy / failure (V)
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7 DESCRIPTION OF THE CASE *(signs & symptoms, possible causes, progression, treatments, relevant medical history, investigations, severity ….)*

8 ONGOING ILLNESS / MEDICAL HISTORY / RISK FACTORS

Personal *(if relevant for the reaction described in this form)*:

Family *(if relevant for the reaction described in this form)*:

9 HISTORY OF ADVERSE REACTION TO PREVIOUS ADMINISTRATION OF VACCINE (V)

Product Name / Therapeutic Class	Date of Occurrence (DD/MM/YYYY)	Reaction	Duration

9 HISTORY OF ADVERSE REACTION TO PREVIOUS ADMINISTRATION OF VACCINE (V)

Comments:

10 COMPLEMENTARY INVESTIGATIONS Type / Results *(indicate unit / attach photocopies if relevant. If patient died please specify if autopsy was performed and what was result)*

11 SERIOUSNESS

☐ **Non-Serious** ☐ **Serious (select at least one criteria below)**

☐ Death *Date of Death:* *Autopsy performed*: Yes ☐ No ☐ Unk ☐

☐ Life threatening

☐ Medically Significant (as per HCP)

☐ Hospitalization or prolongation of hospitalization *Duration of hospitalization:*

☐ Persistent or significant disability or incapacity

☐ Suspected transmission of infectious agent

☐ Congenital anomaly, birth defect

Was this reaction reported to Regulatory Authority? Yes ☐ No ☐

NAME & SIGNATURE :

Sanofi Genzyme
Full Prescribing Information is available upon request:
SANOFI, Kingdom of Saudi Arabia, P.O. Box 9874, Jeddah 21423, K.S.A. Tel: +966-12-669-3318, Fax: +966-12-663-6191

For Medical Information, Please contact: +966-12-669-3318, ksa.medicalinformation@sanofi.com
For Pharmacovigilance, Please contact: +966-54-428-4797, ksa_pharmacovigilance@sanofi.com

To report any Product Technical Complaint, please contact SANOFI Quality Department: Email: KSA_PTC_Reporting@sanofi.com
To report any side effect(s): Saudi Arabia: The National Pharmacovigilance and Drug Safety Centre (NPC)"
• SFDA call center: 19999
• E-mail: npc.drug@sfda.gov.sa
• Website: https://ade.sfda.gov.sa/