独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Imiglucerase (genetical recombination)

November 26, 2025

Non-proprietary name

Imiglucerase (genetical recombination)

Brand name (marketing authorization holder)

Cerezyme for i.v. injection 400 units

(Sanofi K.K.)

Japanese market launch

March 2011

Indications

Improvement of various symptoms of Gaucher disease (anemia, thrombocytopenia, hepatosplenomegaly, and bone symptoms)

Summary of revisions

“Infusion reaction” should be added to the 11.1 Clinically Significant Adverse Reactions section in the 11. ADVERSE REACTIONS section.

In addition, in connection with this addendum, “Infusion reaction” should be added to the precautions in the case where hypersensitivity occurs in the 8. IMPORTANT PRECAUTIONS section.

Investigation results and background of the revision

Cases of “Infusion related reaction” were evaluated. Cases in which a causal relationship between imiglucerase (genetical recombination) and infusion reaction was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Reference: Number of cases* and patient mortalities involving infusion related reaction reported in Japan and overseas

One case has been reported in Japan to date. (A causal relationship between the drug and the event was reasonably possible for this case.)
No patient mortalities have been reported.

A total of 8 cases have been reported overseas to date (including 7 cases in which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported.

*: Cases collected in the PMDA's safety database for drugs

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).