This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.
This English version is intended to be a reference material to provide convenience for users.
In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Imiglucerase (genetical recombination)

November 26, 2025

Therapeutic category

Enzyme preparations

Non-proprietary name

Imiglucerase (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS Administration of this drug may cause hypersensitivity. If clinically significant symptoms occur, administration should be discontinued. After appropriate measures are taken, resumption should be considered while the clinical course is monitored (measures such as prior administration of antihistamine and reducing the infusion rate enabled continuation of administration of this drug).	8. IMPORTANT PRECAUTIONS Administration of this drug may cause hypersensitivity <u>and infusion reaction</u>. If clinically significant symptoms occur, administration should be discontinued. After appropriate measures are taken, resumption should be considered while the clinical course is monitored (measures such as prior administration of antihistamine and reducing the infusion rate enabled continuation of administration of this drug).
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Anaphylaxis Hypersensitivity reactions including pruritus, flushing, urticaria, angioedema, chest discomfort, dyspnoea, wheezing, blood pressure decreased, cyanosis, cough, and hypotension may occur.	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Anaphylaxis, <u>Infusion reaction</u> Hypersensitivity reactions including pruritus, flushing, urticaria, angioedema, chest discomfort, dyspnoea, wheezing, blood pressure decreased, cyanosis, cough, hypotension, <u>and hypertension</u> may occur.

(Note) Designated as a drug requiring preparation of a DRUG Guide for Patients.