

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

Onasemnogene abeparvovec

May 20, 2025

Non-proprietary name

Onasemnogene abeparvovec

Safety measure

PRECAUTIONS should be revised.

Revision in line with the Instructions for Electronic Package Inserts of Regenerative Medical Products, PSEHB Notification No. 0611-13 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (Old instructions)

Revised language is underlined.

Current	Revision
Important Precautions (N/A)	Important Precautions <u>An infusion reaction may occur. Administration of this product should be initiated after arrangements for proper responses to an emergency are ensured in preparation for an infusion reaction.</u>
Defects/Adverse Reactions Clinically significant adverse reactions (N/A)	Defects/Adverse Reactions Clinically significant adverse reactions <u>Infusion reaction:</u> <u>An infusion reaction (rash, urticaria, flushing, vomiting, tachycardia, pyrexia, etc.) including hypersensitivity and anaphylaxis may occur.</u> <u>If an infusion reaction occurs, appropriate measures should be taken.</u>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.