

*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

November 26, 2025

### **Non-proprietary name**

Onasemnogene abeparvovec

### **Safety measure**

PRECAUTIONS should be revised.

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【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
<p><b>IMPORTANT PRECAUTIONS</b></p> <p>Mild increased cardiac troponin I may occur <u>transiently</u> after administration of this product. Cardiac troponin I levels should be measured before administration and <u>for 3 months after administration of this product (weekly for the first month, and then monthly thereafter)</u>. If any abnormality in cardiac troponin I levels is observed, the measurement should be continued until recovery of the levels.</p>	<p><b>IMPORTANT PRECAUTIONS</b></p> <p>Mild increased cardiac troponin I may occur after administration of this product. Cardiac troponin I levels should be measured before administration and <u>within approximately 1 month</u> after administration of this product. If any abnormality in cardiac troponin I levels is observed, the measurement should be continued until recovery of the levels.</p>

【Revision in line with the Instructions for Electronic Package Inserts of Regenerative Medical Products, PSE Notification No. 0607-1 by the Director-General of Pharmaceutical Safety Bureau, MHLW, dated June 7, 2024 (New instructions)】

Revised language is underlined.

Current	Revision
<p><b>8. IMPORTANT PRECAUTIONS</b></p> <p>Mild increased cardiac troponin I may occur <u>transiently</u> after administration of this product. Cardiac troponin I levels should be measured before administration and <u>for 3 months after administration of this product (weekly for the first month, and then monthly thereafter)</u>. If any abnormality in cardiac troponin I levels is observed, the measurement should be continued until recovery of the levels.</p>	<p><b>8. IMPORTANT PRECAUTIONS</b></p> <p>Mild increased cardiac troponin I may occur after administration of this product. Cardiac troponin I levels should be measured before administration and <u>within approximately 1 month</u> after administration of this product. If any abnormality in cardiac troponin I levels is observed, the measurement should be continued until recovery of the levels.</p>