

*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

## Ciltacabtagene autoleucel

March 5, 2025

### **Non-proprietary name**

Ciltacabtagene autoleucel

### **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
<p>Important Precautions</p> <p>Occurrence of lymphoid neoplasm of CAR-positive T-cell origin <u>has</u> been reported in patients treated with <u>ciltacabtagene autoleucl</u>. Although the causal relationship with <u>ciltacabtagene autoleucl</u> is not clear, caution should be exercised regarding the onset of lymphoid neoplasms of T-cell origin.</p>	<p>Important Precautions</p> <p>Occurrences<u>o</u>f lymphoid neoplasm of CAR-positive T-cell origin <u>have</u> been reported in patients treated with <u>regenerative medical products containing CAR-expressing T-cells</u>. Although the causal relationship with <u>the products</u> is not clear, caution should be exercised regarding the onset of lymphoid neoplasms of T-cell origin.</p>

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

Revision in line with the Instructions for Electronic Package Inserts of Regenerative Medical Products, PSB 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>8. IMPORTANT PRECAUTIONS</p> <p>Occurrence of lymphoid neoplasm of CAR-positive T-cell origin <u>has</u> been reported in patients treated with <u>ciltacabtagene autoleucl</u>. Although the causal relationship with <u>ciltacabtagene autoleucl</u> is not clear, caution should be exercised regarding the onset of lymphoid neoplasms of T-cell origin.</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>Occurrences<u>es</u> of lymphoid neoplasm of CAR-positive T-cell origin <u>have</u> been reported in patients treated with <u>regenerative medical products containing CAR-expressing T-cells</u>. Although the causal relationship with <u>the products</u> is not clear, caution should be exercised regarding the onset of lymphoid neoplasms of T-cell origin.</p>

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