

*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

## Axicabtagene ciloleucel, Idecabtagene vicleucel, Tisagenlecleucel, Lisocabtagene maraleucel

March 5, 2025

### **Non-proprietary name**

Axicabtagene ciloleucel

Idecabtagene vicleucel

Tisagenlecleucel

Lisocabtagene maraleucel

### **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 (N/A)</p> <p>Other Precautions <u>Occurrence of lymphoid neoplasm of CAR-positive T-cell origin has been reported in patients treated with another regenerative medical product containing CAR-expressing T-cells.</u></p>	<p>Important Precautions <u>Occurrences of lymphoid neoplasm of CAR-positive T-cell origin have been reported in patients treated with regenerative medical products containing CAR-expressing T-cells. Although the causal relationship with the products is not clear, caution should be exercised regarding the onset of lymphoid neoplasms of T-cell origin.</u></p> <p>Other Precautions (deleted)</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 (N/A)</p> <p>15. OTHER PRECAUTIONS 15.1 Information Based on Clinical Use <u>Occurrence of lymphoid neoplasm of CAR-positive T-cell origin has been reported in patients treated with another regenerative medical product containing CAR-expressing T-cells.</u></p>	<p>8. IMPORTANT PRECAUTIONS <u>Occurrences of lymphoid neoplasm of CAR-positive T-cell origin have been reported in patients treated with regenerative medical products containing CAR-expressing T-cells. Although the causal relationship with the products is not clear, caution should be exercised regarding the onset of lymphoid neoplasms of T-cell origin.</u></p> <p>15. OTHER PRECAUTIONS 15.1 Information Based on Clinical Use (deleted)</p>

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