

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

January 13, 2026

Non-proprietary name

Ciltacabtagene autoleucel

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
Defects/Adverse reactions Clinically Significant Adverse Reactions (newly added)	Defects/Adverse reactions Clinically Significant Adverse Reactions <u>Enterocolitis</u> <u>Enterocolitis considered to be due to an immune reaction may occur. Some cases may result in intestinal perforation. Patients should be carefully monitored. If any abnormalities such as severe or prolonged diarrhoea are observed, appropriate measures should be taken.</u>

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【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
11. DEFECTS/ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (newly added)	11. DEFECTS/ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Enterocolitis</u> <u>Enterocolitis considered to be due to an immune reaction may occur. Some cases may result in intestinal perforation. Patients should be carefully monitored. If any abnormalities such as severe or prolonged diarrhoea are observed, appropriate measures should be taken.</u>