

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

Tisagenlecleucel

January 13, 2026

Non-proprietary name

Tisagenlecleucel

Safety measure

PRECAUTIONS should be revised.

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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 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>11. DEFECTS/ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p> Infection</p> <p> Severe infections caused by bacteria, fungi, or viruses, etc. (sepsis, pneumonia, etc.) may occur. Fatal cases have been reported. In addition, febrile neutropenia may occur. If any abnormalities are observed, appropriate measures such as administration of antibiotics should be taken.</p> | <p>11. DEFECTS/ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p> Infection</p> <p> Severe infections caused by bacteria, fungi, or viruses, etc. (sepsis, pneumonia, etc.) may occur. Fatal cases have been reported. In addition, febrile neutropenia may occur. If any abnormalities are observed, appropriate measures such as administration of antibiotics should be taken. <u>In addition, progressive multifocal leukoencephalopathy (PML) has been reported. If neurological symptoms occur, appropriate tests for the differentiation (cerebrospinal fluid tests and imaging diagnostics with MRI, etc.) should be performed.</u></p> |