Revision of PRECAUTIONS

Ciltacabtagene autoleucel

January 13, 2026

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
Defects/Adverse reactions Clinically Significant Adverse Reactions Infection 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. In addition, in patients who are hepatitis B or C virus carriers or persons with a history of hepatitis B or C, and patients with HIV infection, worsening due to reactivation or increase of the viruses may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as administration of antibiotics should be taken.	Defects/Adverse reactions Clinically Significant Adverse Reactions Infection 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. In addition, in patients who are hepatitis B or C virus carriers or persons with a history of hepatitis B or C, and patients with HIV infection, worsening due to reactivation or increase of the viruses may occur. Patients should be carefully monitored. 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>

【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 Infection 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.	11. DEFECTS/ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Infection 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>