

Published by
Ministry of Health, Labour and Welfare



Translated by
Pharmaceuticals and Medical Devices Agency



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 10, 2024

Non-proprietary name

Ciltacabtagene autoleucel

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Revised language is underlined.

Current	Revision
Important Precautions (N/A)	Important Precautions <u>Occurrence of lymphoid neoplasm of CAR-positive T-cell origin has been reported in patients treated with ciltacabtagene autoleucel.</u> <u>Although the causal relationship with ciltacabtagene autoleucel is not clear, caution should be exercised for the onset of lymphoid neoplasms.</u>

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

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp