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

Axicabtagene ciloleucel Idecabtagene vicleucel Tisagenlecleucel Lisocabtagene maraleucel

March 28, 2024

Non-proprietary name

Axicabtagene ciloleucel
Idecabtagene vicleucel
Tisagenlecleucel
Lisocabtagene maraleucel

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
Other Precautions	Other Precautions
(N/A)	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.

[Reference] Harrison SJ, et al.: Blood. 2023; 142 (Suppl 1): 6939-6940

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