

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

Pembrolizumab (genetical recombination)

July 30, 2025

Therapeutic category

Other antitumor agents

Non-proprietary name

Pembrolizumab (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Vasculitis</u> <u>Large-vessel vasculitis, medium-vessel vasculitis, or small-vessel</u> <u>vasculitis [including anti-neutrophil cytoplasmic antibody (ANCA)-</u> <u>associated vasculitis and IgA vasculitis] may occur.</u>

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