Revision of PRECAUTIONS

Nivolumab (genetical recombination)

September 9, 2025

Therapeutic category

Other antitumor agents

Non-proprietary name

Nivolumab (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

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.

Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS <Common to all indications> (N/A)	8. IMPORTANT PRECAUTIONS <Common to all indications> <u>Tumour lysis syndrome may occur. Patients should be carefully monitored by checking serum electrolyte levels, renal function, etc.</u>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Tumour lysis syndrome</u> <u>If any abnormalities are observed, administration of this drug should be discontinued, appropriate measures (e.g., administration of physiological saline solution and/or hyperuricaemia therapeutic agents, and dialysis) should be taken, and patients should be carefully monitored until recovery from such symptoms.</u>

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