

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.

Attachment 11
July 14, 2026

【Therapeutic category】 429 Other antitumor agents
【Non-proprietary name】 Nivolumab (genetical recombination)
【Safety measure】 PRECAUTIONS should be revised.

A revised description 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>Thrombotic microangiopathy</u> <u>Thrombotic microangiopathy including thrombotic thrombocytopenic purpura may occur. If anaemia accompanied by schizocytes, thrombocytopenia, renal impairment, etc. are observed, appropriate measures should be taken.</u>

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

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.