

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 9
August 25, 2026

【Therapeutic category】 429 Other antitumor agents
【Non-proprietary name】 Ipilimumab (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>Severe oesophagitis</u> <u>Severe oesophagitis considered to be due to an immune reaction may occur.</u> <u>If any abnormalities are observed, appropriate measures including the</u> <u>administration of corticosteroids 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.