

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 8
September 29, 2026

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

A revised description is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Severe gastritis Severe gastritis considered to be due to an immune reaction may occur. If any abnormalities are observed, appropriate measures including the administration of corticosteroids should be taken.	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Severe gastritis, <u>oesophagitis</u> Severe gastritis <u>or oesophagitis</u> considered to be due to an immune reaction may occur. If any abnormalities are observed, appropriate measures including the administration of corticosteroids should be taken.

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.