

*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 5  
September 29, 2026

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

A revised description is underlined.

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