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.

Revision of PRECAUTIONS

Ipilimumab (genetical recombination) Nivolumab (genetical recombination)

July 17, 2024

Therapeutic category

Other antitumor agents

Non-proprietary name

Ipilimumab (genetical recombination)

Nivolumab (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS	11. ADVERSE REACTIONS
11.1 Clinically Significant Adverse Reactions	11.1 Clinically Significant Adverse Reactions
Encephalitis, meningitis	Encephalitis, meningitis <u>, myelitis</u>