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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

Pembrolizumab (genetical recombination)

June 4, 2019

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Pembrolizumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Careful Administration (N/A)	Careful Administration <u>Patients with tuberculosis infection or its history</u>
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically significant Adverse Reactions <u>Tuberculosis:</u> <u>Tuberculosis may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken such as discontinuing this drug.</u>

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