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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)

October 12, 2022

Therapeutic category

Other antitumor agents

Non-proprietary name

Pembrolizumab (genetical recombination)

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS	11. ADVERSE REACTIONS
11.1 Clinically Significant Adverse Reactions	11.1 Clinically Significant Adverse Reactions
(N/A)	<u>Uveitis</u>

(N/A) Not Applicable. No corresponding language is included in the current Precautions.