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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Nivolumab (genetical recombination), pembrolizumab (genetical recombination)

June 14, 2022

Therapeutic category

Other antitumor agents

Non-proprietary name

Nivolumab (genetical recombination), pembrolizumab (genetical recombination)

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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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 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Severe gastritis</u> <u>Severe gastritis considered to be caused by an immune reaction may occur. If any abnormalities are observed, appropriate measures such as administration of corticosteroids should be taken.</u>

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

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