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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

## Nivolumab (genetical recombination)

June 13, 2023

### **Therapeutic category**

Other antitumor agents

### **Non-proprietary name**

Nivolumab (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-General 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 Encephalitis	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Encephalitis, <u>meningitis</u>

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