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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)

March 31, 2020

### **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, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1. Clinically Significant Adverse Reactions Oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme	11. ADVERSE REACTIONS 11.1. Clinically Significant Adverse Reactions <u>Toxic epidermal necrolysis (TEN)</u> , oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme

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