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Translated by  
Pharmaceuticals and Medical Devices Agency



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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

## Durvalumab (genetical recombination)

March 30, 2021

### **Therapeutic category**

Other antitumor agents

### **Non-proprietary name**

Durvalumab (genetical recombination)

### **Safety measure**

Precautions should be revised in the package insert.

**Pharmaceuticals and Medical Devices Agency**

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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 (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant adverse Reactions <u>Immune thrombocytopenic purpura</u>

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

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