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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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