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Revision of Precautions

Baricitinib

September 24, 2019

Therapeutic category

Miscellaneous metabolism agents-miscellaneous

Non-proprietary name

Baricitinib

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
8. IMPORTANT PRECAUTIONS Onset of deep vein thrombosis and pulmonary embolism has been reported in clinical studies. This drug should be administered carefully with patients under close monitoring. If any abnormalities are observed, administration of this drug should be discontinued immediately and appropriate measures should be taken. 11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	8. IMPORTANT PRECAUTIONS (deleted) 11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Venous thromboembolism Pulmonary embolism and deep vein thrombosis may occur.

N/A: Not Applicable, because the section is not included in the current package insert.

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