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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Fingolimod hydrochloride

December 17, 2021

Therapeutic category

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Non-proprietary name

Fingolimod hydrochloride

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 Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS	8. IMPORTANT PRECAUTIONS Thrombocytopenia may occur. Blood tests (such as blood cell count) should be performed prior to, and periodically during, administration of this drug. Cases of severe exacerbation of disease compared with before administration have been reported following discontinuation of this drug, generally observed up to 24 weeks after discontinuation. When administration is discontinued, caution should be exercised for severe aggravation of disease.
11.1 Clinically Significant Adverse Reactions (N/A)	11.1 Clinically Significant Adverse Reactions Thrombocytopenia

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

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