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Pharmaceuticals and Medical Devices Agency

Revision of PRECAUTIONS

Preparations containing HMG-CoA reductase inhibitor

July 20, 2023

Therapeutic category

Agents for hyperlipidemias

Other cardiovascular agents

Non-proprietary name

Atorvastatin calcium hydrate

Ezetimibe/atorvastatin calcium hydrate

Ezetimibe/rosuvastatin calcium

Simvastatin

Pitavastatin calcium hydrate

Pitavastatin calcium hydrate/ezetimibe

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Pravastatin sodium

Fluvastatin sodium

Rosuvastatin calcium

Amlodipine besilate/atorvastatin calcium hydrate

Safety measure

PRECAUTIONS should be revised.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director-General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Careful Administration (N/A)	Careful Administration <u>Patients with myasthenia gravis or a history of it [Exacerbation or relapse of myasthenia gravis (ocular or systemic) may occur.]</u>
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Myasthenia gravis:</u> <u>Myasthenia gravis (ocular or systemic) may occur or worsen. Patients should be carefully monitored, and if any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken.</u>

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

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

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9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. Patients with myasthenia gravis or a history of it Exacerbation or relapse of myasthenia gravis (ocular or systemic) may occur.
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Myasthenia gravis Myasthenia gravis (ocular or systemic) may occur or worsen.

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

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