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
Pravastatin sodium
Fluvastatin sodium
Rosuvastatin calcium
Amlodipine besilate/atorvastatin calcium hydrate

Safety measure
PRECAUTIONS should be revised.
<table>
<thead>
<tr>
<th>Current</th>
<th>Revision</th>
</tr>
</thead>
</table>
| Careful Administration  
(N/A) | Careful Administration  
Patients with myasthenia gravis or a history of it [Exacerbation or relapse of myasthenia gravis (ocular or systemic) may occur.] |
| Adverse Reactions  
Clinically Significant Adverse Reactions  
(N/A) | Adverse Reactions  
Clinically Significant Adverse Reactions  
Myasthenia gravis:  
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. |

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.
### 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

#### 9.1 Patients with Complication or History of Diseases, etc.

(N/A)

### 11. ADVERSE REACTIONS

#### 11.1 Clinically Significant Adverse Reactions

(N/A)

---

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

- **Myasthenia gravis**: Myasthenia gravis (ocular or systemic) may occur or worsen.