



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Amlodipine besilate/Atorvastatin calcium hydrate

October 18, 2016

Non-proprietary name

- Amlodipine besilate/Atorvastatin calcium hydrate

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

There have been reports of Immune-mediated necrotizing myopathy characterized by such as proximal muscle weakness, elevated CK (CPK), muscle fiber necrosis without inflammation, and anti-HMG-CoA reductase (HMGCR) antibody positive, which persisted despite discontinuation of treatment. Patients should be carefully monitored. Improvement in immune-mediated necrotizing myopathy has been reported after administration of immunosuppressive agents.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Immune-mediated necrotizing myopathy
Immune-mediated necrotizing myopathy may occur. Patients should be carefully monitored.
If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be adopted.

Pharmaceuticals and Medical Devices Agency

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