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Revision of Precautions

Atorvastatin calcium hydrate

Ezetimibe/atorvastatin calcium hydrate

Pravastatin sodium

Amlodipine basilate/atorvastatin calcium hydrate

October 16, 2018

Non-proprietary name

Atorvastatin calcium hydrate

Ezetimibe/atorvastatin calcium hydrate

Pravastatin sodium

Amlodipine basilate/atorvastatin calcium hydrate

Safety measure

Precautions should be revised in the package insert.

The following language should be deleted from the Relative Contraindications section:

This drug should be co-administered with fibrates in patients with abnormal renal function values only when such use is deemed to be absolutely necessary for treatment.

The following language should be added to the Important Precautions section (revised language is underlined):

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This drug should be co-administered with fibrates in patients with abnormal renal function values only when such use is deemed to be absolutely necessary for treatment. Rhabdomyolysis accompanied by rapid deterioration of renal function tends to occur. When administration of this drug in combination with fibrates is unavoidable, clinical laboratory tests examining renal function should be performed periodically. If appearance of subjective symptoms (myalgia, feeling of weakness), increased CK (CPK) level, increased blood or urine myoglobin level, or signs of diminished renal function such as increased serum creatinine level is observed, administration of this drug combination should be discontinued immediately.

The following language should be deleted from the Relative Contraindications for Co-administration subsection of the Interactions section:

Fibrates (e.g., bezafibrate)

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