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*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

## Simvastatin

October 16, 2018

### **Non-proprietary name**

Simvastatin

### **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 dosage of this drug should not exceed 10 mg/day.

The following language should be added to the Careful Administration section (revised language is underlined):

Patients receiving fibrates (e.g., bezafibrate)

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

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 dosage of this drug should not exceed 10 mg/day. Rhabdomyolysis accompanied by rapid deterioration of renal function tends to occur. When administration of this drug in

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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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