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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

## Fenofibrate

## Bezafibrate

October 16, 2018

### **Non-proprietary name**

Fenofibrate

Bezafibrate

### **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 HMG-CoA reductase inhibitors 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):

This drug should be co-administered with HMG-CoA reductase inhibitors 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 HMG-CoA reductase inhibitors is unavoidable, initiation of treatment with this drug should begin at a low dose and clinical laboratory tests examining renal function should be performed periodically. If

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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:

HMG-CoA reductase inhibitors (e.g., pravastatin sodium, simvastatin, fluvastatin sodium)

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