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Revision of Precautions

Pemafibrate

October 16, 2018

Non-proprietary name

Pemafibrate

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):

<u>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 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 levels is observed, administration of this drug combination</u>

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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)

The following language should be added to the Precautions for Co-administration section (revised language is underlined):

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

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