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Revision of Precautions

Pemafibrate

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Therapeutic category

Agents for hyperlipidemias

Non-proprietary name

Pemafibrate

Safety measure

Precautions should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Contraindications Patients with renal impairment whose serum creatinine value is greater than or equal to 2.5 mg/dL or creatinine clearance is less than 40 mL/min [Rhabdomyolysis may occur.]	Contraindications (deleted)
Precautions concerning Dosage and Administration Rhabdomyolysis accompanied by rapid deterioration of renal function may occur. When using this drug, patients should be monitored for the renal function. If the serum creatinine value is greater than or equal to 2.5 mg/dL, administration of this drug should be discontinued, and if the value is greater than or equal to 1.5 mg/dL and less than 2.5 mg/dL, administration of this drug should be initiated at a low dose or the dosing interval should be prolonged.	Precautions concerning Dosage and Administration Rhabdomyolysis accompanied by rapid deterioration of renal function may occur. When using this drug, patients should be monitored for the renal function. If the eGFR is less than 30 mL/min/1.73 m^2, administration of this drug should be initiated at a low dose or the dosing interval should be prolonged. In addition, the maximum daily dose should be limited to 0.2 mg.
Careful Administration Patients with renal impairment whose serum creatinine value is greater than or equal to 1.5 mg/dL and less than 2.5 mg/dL or whose creatinine clearance is greater than or equal to 40 mL/min and less than 60 mL/min [Rhabdomyolysis may occur.]	Careful Administration Patients with renal impairment whose eGFR is less than 30 mL/min/1.73 m^2 [Rhabdomyolysis may occur.]

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Important Precautions In patients with renal impairment, rhabdomyolysis accompanied by rapid deterioration of renal function may occur. When using this drug, patients should be monitored for the renal function. If the serum creatinine value is greater than or equal to 2.5 mg/dL, administration of this drug should be discontinued, and if the value is greater than or equal to 1.5 mg/dL and less than 2.5 mg/dL, appropriate measures should be taken such as dose reduction or prolongation of the dosing interval of this drug.	Important Precautions In patients with renal impairment, rhabdomyolysis accompanied by rapid deterioration of renal function may occur. When using this drug, patients should be monitored for the renal function. If the eGFR is less than 30 mL/min/1.73 m^2, appropriate measures should be taken such as dose reduction or prolongation of the dosing interval of this drug.

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