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Pharmaceuticals and Medical Devices Agency



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

Lomitapide mesilate

September 7, 2021

Therapeutic category

Agents for hyperlipidemias

Non-proprietary name

Lomitapide mesilate

Safety measure

Precautions should be revised in the package insert.

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			Revised		
Drug Interactions Contraindications for Co-Administration			Drug Interactions Contraindications for Co-Administration		
Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Moderate CYP3A inhibitors (aprepitant, atazanavir, ciprofloxacin, crizotinib, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil, <u>istradefylline</u> , miconazole (gel/injections), tofisopam)	The blood concentration of this drug may increase markedly.	These drugs inhibit CYP3A and thereby inhibit metabolism of lomitapide mesilate.	Moderate CYP3A inhibitors (aprepitant, atazanavir, ciprofloxacin, crizotinib, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil, miconazole (gel/injections), tofisopam)	The blood concentration of this drug may increase markedly.	These drugs inhibit CYP3A and thereby inhibit metabolism of lomitapide mesilate.

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Precautions for Co-Administration			Precautions for Co-Administration		
Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Weak CYP3A inhibitors (atorvastatin, cimetidine, cilostazol, oral contraceptives, etc.)	The blood concentration of this drug may increase. Co-administered with weak CYP3A inhibitors requires caution. The dosage of this drug should be reduced and patients should be closely monitored.	These drugs inhibit CYP3A and thereby inhibit metabolism of lomitapide mesilate.	Weak CYP3A inhibitors (atorvastatin, cimetidine, cilostazol, oral contraceptives, <u>istradefylline</u> , etc.)	The blood concentration of this drug may increase. Co-administered with weak CYP3A inhibitors requires caution. The dosage of this drug should be reduced and patients should be closely monitored.	These drugs inhibit CYP3A and thereby inhibit metabolism of lomitapide mesilate.

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