

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Tadalafil (pulmonary arterial hypertension)

March 17, 2026

Therapeutic category

Other cardiovascular agents

Non-proprietary name

Tadalafil (pulmonary arterial hypertension)

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current			Revision		
<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving drugs that strongly inhibit cytochrome P450 3A4 (CYP3A4) (itraconazole, preparations containing ritonavir, atazanavir, indinavir, nelfinavir, saquinavir, preparations containing darunavir, clarithromycin, telaprevir, preparations containing cobicistat, ensitrelvir)</p>			<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>Patients receiving drugs that strongly inhibit cytochrome P450 3A4 (CYP3A4) (itraconazole, preparations containing ritonavir, atazanavir, indinavir, nelfinavir, saquinavir, preparations containing darunavir, clarithromycin, telaprevir, preparations containing cobicistat, ensitrelvir, <u>ceritinib</u>)</p>		
<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p>			<p>10. INTERACTIONS</p> <p>10.1 Contraindications for Co-administration (Do not co-administer with the following.)</p>		
Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
<p>Drugs that strongly inhibit CYP3A4</p> <p>Itraconazole</p> <p>Preparations containing ritonavir</p> <p>Atazanavir</p> <p>Indinavir</p> <p>Nelfinavir</p> <p>Saquinavir</p> <p>Preparations containing darunavir</p> <p>Clarithromycin</p> <p>Telaprevir</p>	<p>It has been reported that co-administration with ketoconazole (400 mg/day: oral dosage form, not marketed in Japan), which has a strong inhibitory effect on CYP3A4, increases the AUC and Cmax of this drug (20 mg) by 312% and 22%,</p>	<p>These drugs are expected to severely reduce the clearance of this drug by strongly inhibiting CYP3A4, leading to an increase in the plasma concentration of this drug. Patients receiving these drugs have been</p>	<p>Drugs that strongly inhibit CYP3A4</p> <p>Itraconazole</p> <p>Preparations containing ritonavir</p> <p>Atazanavir</p> <p>Indinavir</p> <p>Nelfinavir</p> <p>Saquinavir</p> <p>Preparations containing darunavir</p> <p>Clarithromycin</p> <p>Telaprevir</p>	<p>It has been reported that co-administration with ketoconazole (400 mg/day: oral dosage form, not marketed in Japan), which has a strong inhibitory effect on CYP3A4, increases the AUC and Cmax of this drug (20 mg) by 312% and 22%,</p>	<p>These drugs are expected to severely reduce the clearance of this drug by strongly inhibiting CYP3A4, leading to an increase in the plasma concentration of this drug. Patients receiving these drugs have been</p>

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Preparations containing cobicistat Ensitrelvir	respectively. In addition, it has been reported that co-administration with ritonavir (200 mg twice daily) increases the AUC of this drug (20 mg) by 124%.	excluded from clinical studies.	Preparations containing cobicistat Ensitrelvir <u>Ceritinib</u>	respectively. In addition, it has been reported that co-administration with ritonavir (200 mg twice daily) increases the AUC of this drug (20 mg) by 124%.	excluded from clinical studies.