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Translated by
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

Sildenafil citrate (preparations indicated for pulmonary arterial hypertension)

January 26, 2021

Therapeutic category

Other cardiovascular agents

Non-proprietary name

Sildenafil citrate

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current			Revision
2. CONTRAINDICATIONS <u>Patients receiving amiodarone hydrochloride (oral dosage form)</u>			2. CONTRAINDICATIONS (Deleted)
10. INTERACTIONS 10.1 Contraindications for Co-administration			10. INTERACTIONS 10.1 Contraindications for Co-administration (Deleted)
Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	
<u>Amiodarone hydrochloride (oral dosage form)</u>	<u>The QTc prolongation effects by amiodarone hydrochloride could be augmented.</u>	<u>Mechanism is unknown. Risk of QTc prolongation with co-administration of similar drugs and amiodarone hydrochloride has been reported.</u>	

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<p>10.2 Precautions for Co-administration (N/A)</p>	<p>10.2 Precautions for Co-administration</p>		
	<p>Drugs</p>	<p>Signs, Symptoms, and Treatment</p>	<p>Mechanism and Risk Factors</p>
	<p><u>Amiodarone hydrochloride</u></p>	<p><u>The QTc prolongation effects by amiodarone hydrochloride could be augmented.</u></p>	<p><u>Mechanism is unknown. Risk of QTc prolongation with co-administration of similar drugs and amiodarone hydrochloride has been reported.</u></p>

N/A: Not Applicable, because the section is not included in the current package insert.

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