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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

Amiodarone hydrochloride (oral dosage form)

January 26, 2021

Therapeutic category

Antiarrhythmic agents

Non-proprietary name

Amiodarone hydrochloride

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	Revision												
<p>Contraindications</p> <p>Patients receiving ritonavir, saquinavir, saquinavir mesilate, indinavir sulfate ethanolate, nelfinavir mesilate, sparfloxacin, moxifloxacin hydrochloride, vardenafil hydrochloride hydrate, sildenafil citrate, toremifene citrate, telaprevir, fingolimod hydrochloride, or eliglustat tartrate</p> <p>Interactions</p> <p>Contraindications for Co-administration</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Drugs</th> <th style="width: 33%;">Signs, Symptoms, and Treatment</th> <th style="width: 33%;">Mechanism and Risk Factors</th> </tr> </thead> <tbody> <tr> <td>Vardenafil hydrochloride hydrate, sildenafil citrate</td> <td>Prolonged QT may occur.</td> <td>QT prolongation effects may incrementally increase with co-administration.</td> </tr> </tbody> </table>	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	Vardenafil hydrochloride hydrate, sildenafil citrate	Prolonged QT may occur.	QT prolongation effects may incrementally increase with co-administration.	<p>Contraindications</p> <p>Patients receiving ritonavir, saquinavir, saquinavir mesilate, indinavir sulfate ethanolate, nelfinavir mesilate, sparfloxacin, moxifloxacin hydrochloride, vardenafil hydrochloride hydrate, sildenafil citrate <u>(indicated for erectile dysfunction)</u>, toremifene citrate, telaprevir, fingolimod hydrochloride, or eliglustat tartrate</p> <p>Interactions</p> <p>Contraindications for Co-administration</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Drugs</th> <th style="width: 33%;">Signs, Symptoms, and Treatment</th> <th style="width: 33%;">Mechanism and Risk Factors</th> </tr> </thead> <tbody> <tr> <td>Vardenafil hydrochloride hydrate, sildenafil citrate <u>(indicated for erectile dysfunction)</u></td> <td>Prolonged QT may occur.</td> <td>QT prolongation effects may incrementally increase with co-administration.</td> </tr> </tbody> </table>	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	Vardenafil hydrochloride hydrate, sildenafil citrate <u>(indicated for erectile dysfunction)</u>	Prolonged QT may occur.	QT prolongation effects may incrementally increase with co-administration.
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Precautions for Co-administration (N/A)	Precautions for Co-administration		
	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
	<u>Sildenafil citrate</u> (indicated for <u>pulmonary arterial hypertension</u>)	<u>Prolonged QT may occur.</u>	<u>QT prolongation effects may incrementally increase with co-administration.</u>

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
<p>2. CONTRAINDICATIONS</p> <p>Patients receiving ritonavir, saquinavir, saquinavir mesilate, indinavir sulfate ethanolate, nelfinavir mesilate, sparfloxacin, moxifloxacin hydrochloride, vardenafil hydrochloride hydrate, sildenafil citrate, toremifene citrate, telaprevir, fingolimod hydrochloride, or eliglustat tartrate</p>	<p>2. CONTRAINDICATIONS</p> <p>Patients receiving ritonavir, saquinavir, saquinavir mesilate, indinavir sulfate ethanolate, nelfinavir mesilate, sparfloxacin, moxifloxacin hydrochloride, vardenafil hydrochloride hydrate, <u>sildenafil citrate (indicated for erectile dysfunction)</u>, toremifene citrate, telaprevir, fingolimod hydrochloride, or eliglustat tartrate</p>

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10. INTERACTIONS

10.1 Contraindications for Co-administration

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Vardenafil hydrochloride hydrate, sildenafil citrate	Prolonged QT may occur.	QT prolongation effects may incrementally increase with co-administration.

10.2 Precautions for Co-administration

(N/A)

10. INTERACTIONS

10.1 Contraindications for Co-administration

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Vardenafil hydrochloride hydrate, sildenafil citrate <u>(indicated for erectile dysfunction)</u>	Prolonged QT may occur.	QT prolongation effects may incrementally increase with co-administration.

10.2 Precautions for Co-administration

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
<u>Sildenafil citrate (indicated for pulmonary arterial hypertension)</u>	<u>Prolonged QT may occur.</u>	<u>QT prolongation effects may incrementally increase with co-administration.</u>

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