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62

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.

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	Current			Revision	
Contraindications			Contraindications		
Patients receiving ritonavir, saquinavir, saquinavir mesilate,			Patients receiving ritonavir, saquinavir, saquinavir mesilate, indinav		
indinavir sulfate ethanolate, nelfinavir mesilate, sparfloxacin,			sulfate ethanolate, nelfinavir mesilate, sparfloxacin, moxifloxad		
moxifloxacin hydrochloride, vardenafil hydrochloride hydrate,		hydrochloride, vardenafil hydrochloride hydrate, sildenafil citra			
sildenafil citrate, toremifene citrate, telaprevir, fingolimod		(indicated for erectile dysfunction), toremifene citrate, telapre-			
hydrochloride, or eliglustat tartrate		fingolimod hydrochloride, or eliglustat tartrate			
Interactions			Interactions		
Contraindications for Co-administration		Contraindications for Co-administration			
Drugs	Signs, Symptoms,	Mechanism and	Drugs	Signs, Symptoms,	Mechanism and
	and Treatment	Risk Factors		and Treatment	Risk Factors
Vardenafil	Prolonged QT may	QT prolongation	Vardenafil	Prolonged QT may	QT prolongation
hydrochloride	occur.	effects may	hydrochloride	occur.	effects may
hydrate, sildenafil		incrementally	hydrate, sildenafil		incrementally
citrate		increase with co-	citrate <u>(indicated for</u>		increase with co-
		administration.	erectile dysfunction)		administration.

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.

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Precautions for Co-administration	Precautions for Co-adr	ninistration	
(N/A)	Drugs	Signs, Symptoms,	Mechanism and
		and Treatment	Risk Factors
	Sildenafil citrate	Prolonged QT may	QT prolongation
	(indicated for	occur.	effects may
	pulmonary arterial		incrementally
	hypertension)		increase with co-
			administration.
		•	·

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

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0. INTERACTIONS			10. INTERACTIONS		
10.1 Contraindications for Co-administration			10.1 Contraindications for Co-administration		
Drugs	Signs, Symptoms,	Mechanism and	Drugs	Signs, Symptoms,	Mechanism and
	and Treatment	Risk Factors		and Treatment	Risk Factors
Vardenafil	Prolonged QT may	QT prolongation	Vardenafil	Prolonged QT may	QT prolongation
hydrochloride	occur.	effects may	hydrochloride	occur.	effects may
hydrate, sildenafil		incrementally	hydrate, sildenafil		incrementally
citrate		increase with co-	citrate (indicated for		increase with co-
		administration.	erectile dysfunction)		administration.
10.2 Precautions for Co-administration (N/A)					
-	Co-administration		10.2 Precautions for Co	o-administration Signs, Symptoms, and Treatment	Mechanism and Risk Factors
-	Co-administration			Signs, Symptoms,	
-	Co-administration		Drugs	Signs, Symptoms, and Treatment	Risk Factors
-	Co-administration		Drugs <u>Sildenafil citrate</u>	Signs, Symptoms, and Treatment <u>Prolonged QT may</u>	Risk Factors
-	Co-administration		Drugs Sildenafil citrate (indicated for	Signs, Symptoms, and Treatment <u>Prolonged QT may</u>	QT prolongation effects may

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

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