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.

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Revision of Precautions

Itraconazole

May 20, 2025

Therapeutic category

Other chemotherapeutics

Non-proprietary name

Itraconazole

Safety measure

PRECAUTIONS should be revised.

Current

2. CONTRAINDICATIONS (This drug is contraindicated to the following

Patients receiving the following drugs: Pimozide, quinidine, bepridil, triazolam, simvastatin, azelnidipine, azelnidipine/olmesartan medoxomil, nisoldipine, ergotamine/caffeine/isopropylantipyrine, dihydroergotamine, ergometrine, methylergometrine, vardenafil, eplerenone, blonanserin, sildenafil (Revatio), tadalafil (Adcirca), suvorexant, ibrutinib, ticagrelor, lomitapide, ivabradine, venetoclax [during its dose escalation phase for relapsed or refractory chronic lymphocytic leukemia (including small lymphocytic lymphoma)], lurasidone hydrochloride, anamorelin hydrochloride, finerenone, isavuconazonium sulfate, aliskiren, dabigatran, rivaroxaban, riociguat

10. INTERACTIONS

patients.)

10.1 Contraindications for Co-administration (Do not co-administer with the following.)

and removing.)			
Drugs	Signs, symptoms, and	Mechanism/risk	
	treatment	factors	
Riociguat	Itraconazole may increase the	It is considered that	
	blood concentration of	the clearance of	
	riociguat. (It has been reported	riociguat is	
	as follows: When co-	decreased by the	
	administered with	inhibitory activity of	
	ketoconazole, the AUC and	itraconazole against	
	C _{max} of riociguat were	CYP3A4 and P-	
	increased by 150% and 46%,	glycoprotein.	
	respectively. In addition, the		

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Revision

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10. INTERACTIONS

patients.)

10.1 Contraindications for Co-administration (Do not co-administer with the following.)
(deleted)

elimination half-life was	
prolonged, and the clearance	
was also decreased.)	

10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)
(N/A)

10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)

Bright Signs, symptoms, and treatment Riociguat Riociguat Itraconazole may increase the blood concentration of riociguat. (It has been reported as follows: When coadministered with ketoconazole, the AUC and Cmax of riociguat were increased by 150% and 46%, respectively. In addition, the elimination half-life was prolonged.) When coadministration with itraconazole is necessary, patients should be monitored for their condition and dose reduction of riociguat should be considered as necessary.			<u> </u>
blood concentration of riociguat. (It has been reported as follows: When coadministered with ketoconazole, the AUC and Cmax of riociguat were increased by 150% and 46%, respectively. In addition, the elimination half-life was prolonged.) When coadministration with itraconazole is necessary, patients should be monitored for their condition and dose reduction of riociguat should	Drugs	, , ,	
	Riociguat	blood concentration of riociguat. (It has been reported as follows: When coadministered with ketoconazole, the AUC and Cmax of riociguat were increased by 150% and 46%, respectively. In addition, the elimination half-life was prolonged.) When coadministration with itraconazole is necessary, patients should be monitored for their condition and dose	the clearance of riociguat is decreased by the inhibitory activity of itraconazole against CYP1A1 and

(N/A) Not Applicable. No corresponding language is included in the current PRECAUTIONS.