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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

Itraconazole (injections)

October 12, 2022

Therapeutic category

Other chemotherapeutics

Non-proprietary name

Itraconazole

Safety measure

Precautions should be revised.

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
Important Precautions	Important Precautions
(N/A)	Hypokalaemia may occur. Periodic blood electrolyte test should be
	performed.
Adverse Reactions	Adverse Reactions
Clinically Significant Adverse Reactions	Clinically Significant Adverse Reactions
(N/A)	<u>Hypokalaemia:</u>
	Hypokalaemia may occur. Patients should be carefully monitored,
	and if any abnormalities are observed, appropriate measures such
	as discontinuing administration should be taken.

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