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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

Itraconazole (oral solution)

October 12, 2022

Therapeutic category

Other chemotherapeutics

Non-proprietary name

Itraconazole

Safety measure

Precautions should be revised.

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

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

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS (N/A)</p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions</p>	<p>8. IMPORTANT PRECAUTIONS <u>Hypokalaemia may occur. Periodic blood electrolyte test should be performed.</u></p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions</p>

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(N/A)	<u>Hypokalaemia</u>
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