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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

February 15, 2024

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
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Pseudoaldosteronism:</u> <u>Hypokalaemia, increased blood pressure, retention of sodium/body fluid, oedema, increased weight, etc. may occur. Patients should be carefully monitored, and if any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken.</u>

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, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Pseudoaldosteronism</u> <u>Hypokalaemia, increased blood pressure, retention of sodium/body fluid, oedema, increased weight, etc. may occur.</u>

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