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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

Fosravuconazole L-lysine ethanolate

February 25, 2020

Therapeutic category

Chemotherapeutics-miscellaneous

Non-proprietary name

Fosravuconazole L-lysine ethanolate

Safety measure

Precautions should be revised in the package insert.

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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>Erythema multiforme:</u> <u>Erythema multiforme may occur. Patients should be carefully monitored and if any abnormalities are observed, appropriate measures should be taken such as discontinuing this drug.</u>

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

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