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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

Apalutamide

October 12, 2013

Therapeutic category

Other antitumor agents

Non-proprietary name

Apalutamide

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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
<p>8. IMPORTANT PRECAUTIONS</p> <p>Severe skin disorders may occur. If a rash occurs, a dermatologist should be consulted at an early stage, and temporary discontinuation or discontinuation of this drug should be considered. Patients should be instructed to immediately seek medical attention if any skin abnormalities are observed.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>Severe skin disorders <u>and drug-induced hypersensitivity syndrome</u> may occur. If a rash occurs, a dermatologist should be consulted at an early stage, and temporary discontinuation or discontinuation of this drug should be considered. Patients should be instructed to immediately seek medical attention if any skin abnormalities are observed.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Drug-induced hypersensitivity syndrome</u> <u>Initial symptoms of rash and pyrexia, followed by serious delayed symptoms of hypersensitivity accompanied by hepatic impairment, swollen lymph nodes, increased white blood cell, eosinophilia, and appearance of atypical lymphocytes may occur. Symptoms are often accompanied by virus reactivation, such as human herpes virus type 6 (HHV-6). Caution is required for recurrence or prolongation of rash, pyrexia, hepatic impairment, etc. that may occur even after discontinuation of administration.</u></p>

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

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