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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

May 19, 2020

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Apalutamide

Safety measure

Precautions should be revised in the package insert.

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
<p>Important Precautions (N/A)</p>	<p>Important Precautions <u>Severe skin disorders such as toxic epidermal necrolysis (TEN), erythema multiforme 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</u></p>
<p>Adverse Reactions Clinically Significant Adverse Reactions Severe skin disorders: Severe skin disorder such as erythema multiforme may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken such as discontinuing this drug.</p>	<p>Adverse Reactions Clinically Significant Adverse Reactions Severe skin disorders: Severe skin disorder such as <u>toxic epidermal necrolysis (TEN)</u>, erythema multiforme may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken such as discontinuing this drug.</p>

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

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