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*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

## Enzalutamide

November 15, 2019

### **Therapeutic category**

Antineoplastics-miscellaneous

### **Non-proprietary name**

Apalutamide, enzalutamide

### **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
Careful Administration (N/A)	Careful Administration <u>Patients with interstitial lung disease or a history of the disease</u>
Important Precautions (N/A)	Important Precautions <u>Interstitial lung disease may occur. When using this drug, patients should be carefully monitored for initial symptoms (such as breathlessness, dyspnoea, cough, and pyrexia) and by performing a chest X-ray, etc. Patients should be adequately informed of adverse reactions associated with this drug and instructed to immediately contact medical institutions when they experience any initial symptoms of the disease.</u>
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Interstitial lung disease:</u> <u>Interstitial lung disease may occur. Patients should be carefully monitored. If any abnormalities are observed, this drug should be discontinued and a chest CT scan or serum marker test, etc. should be performed as necessary, and appropriate measures should be taken.</u>

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

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