Revision of PRECAUTIONS
Apalutamide

October 12, 2013

Therapeutic category
Other antitumor agents

Non-proprietary name
Apalutamide

Safety measure
PRECAUTIONS should be revised.
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.

<table>
<thead>
<tr>
<th>Current</th>
<th>Revision</th>
</tr>
</thead>
</table>
| **8. IMPORTANT PRECAUTIONS**
  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. | **8. IMPORTANT PRECAUTIONS**
Severe skin disorders and drug-induced hypersensitivity syndrome 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. |

| **11. ADVERSE REACTIONS**
11.1 Clinically Significant Adverse Reactions (N/A) | **11. ADVERSE REACTIONS**
11.1 Clinically Significant Adverse Reactions
Drug-induced hypersensitivity syndrome
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. |

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