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.
<table>
<thead>
<tr>
<th>Current</th>
<th>Revision</th>
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| Careful Administration (N/A) | Careful Administration  
Patients with interstitial lung disease or a history of the disease  |
| Important Precautions (N/A) | Important Precautions  
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. |
| Adverse Reactions Clinically Significant Adverse Reactions (N/A) | Adverse Reactions Clinically Significant Adverse Reactions  
Interstitial lung disease:  
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. |

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