



Summary of Investigation Results

Apalutamide

November 15, 2019

Non-proprietary name

Apalutamide

Branded name (Marketing authorization holder)

Erleada Tablets 60 mg (Janssen Pharmaceutical K.K.)

Indications

Castration-resistant prostate cancer without remote metastasis

Summary of revisions

1. "Patients with interstitial lung disease or a history of the disease" should be added to the Careful Administration section.
2. A cautionary statement for interstitial lung disease should be added to the Important Precautions section.
3. "Interstitial lung disease" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of interstitial lung disease have been reported in patients treated with apalutamide in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.



Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 4 cases involving interstitial lung disease have been reported to date (including 2 cases for which a causal relationship between the drug and event could not be ruled out).

One instance of patient mortality has been reported to date (A causal relationship between the drug and the death subsequent to event could not be ruled out for this case.)

(Japanese market launch: May 2019)