



Summary of Investigation Results

Enzalutamide

November 15, 2019

Non-proprietary name

Enzalutamide

Branded name (Marketing authorization holder)

Xtandi Capsules 40 mg, Xtandi Tablets 40 mg, 80 mg (Astellas Pharma Inc.)

Indications

Castration-resistant prostate cancer

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 enzalutamide 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 19 cases involving interstitial lung disease have been reported to date (including 5 cases for which a causal relationship between the drug and event could not be ruled out). A total of 3 patient mortalities have been reported to date (A causal relationship between the drug and the death subsequent to event could not be established in any of these cases.)