



Summary of Investigation Results

Apalutamide

October 12, 2023

Non-proprietary name

Apalutamide

Brand name (marketing authorization holder)

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

Japanese market launch

May 2019

Indications

- Castration-resistant prostate cancer without remote metastasis
- Metastatic prostate cancer

Summary of revisions

1. “Drug-induced hypersensitivity syndrome” should be added to the language concerning severe skin disorders in the IMPORTANT PRECAUTIONS section.
2. “Drug-induced hypersensitivity syndrome” should be added to the Clinically Significant Adverse Reactions section in ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving drug-induced hypersensitivity syndrome were evaluated. Cases for which a causal relationship between apalutamide and drug-induced hypersensitivity syndrome was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was

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necessary.

Reference: Number of cases* and patient mortalities involving drug-induced hypersensitivity syndrome reported in Japan and overseas

A total of 4 cases have been reported in Japan to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible).

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

A total of 29 cases have been reported overseas to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported overseas to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).