



Summary of Investigation Results

Fulvestrant

May 19, 2020

Non-proprietary name

Fulvestrant

Branded name (Marketing authorization holder)

Faslodex Intramuscular Injection 250 mg (AstraZeneca K.K)

Indications

Breast cancer

Summary of revisions

“Injection site necrosis, ulcer” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of injection site necrosis, ulcer have been reported in patients treated with fulvestrant in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.



This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

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

A total of 6 cases involving injection site necrosis, ulcer have been reported to date (including 5 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported to date.

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).