独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

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Summary of Investigation Results

Fulvestrant

July 30, 2025

Non-proprietary name

Fulvestrant

Brand name (marketing authorization holder)

Faslodex Intramuscular Injection 250 mg (AstraZeneca K.K.)

Japanese market launch

November 2011

Indications

Breast cancer

Summary of revisions

“Anaphylaxis” should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving anaphylaxis were evaluated. Cases for which a causal relationship between fulvestrant and anaphylaxis 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 necessary.

Reference: Number of cases* and patient mortalities involving anaphylaxis reported in Japan

A total of 21 cases have been reported to date (including 6 cases for which a causal

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relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported to date.

*Cases collected in the PMDA's safety database for drugs

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).