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

Lubiprostone

October 22, 2025

Non-proprietary name

Lubiprostone

Brand name (marketing authorization holder)

Amitiza Capsules 12 μg, Amitiza Capsules 24 μg (Viatris Pharmaceuticals Japan G.K.)

Japanese market launch

Capsules 12 μg: November 2018

Capsules 24 μg: November 2012

Indications

Chronic constipation (excluding constipation due to organic disease)

Summary of revisions

The section "11.1 Clinically Significant Adverse Reactions" in "11. ADVERSE REACTIONS" has been newly created, and "anaphylaxis" has been added.

Investigation results and background of the revision

Cases involving anaphylaxis were evaluated. Cases in which a causal relationship between lubiprostone 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

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A total of 12 cases have been reported to date (including 5 cases in which a causal 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).