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.

Summary of Investigation Results

Edoxaban tosilate hydrate

January 29, 2025

Non-proprietary name

Edoxaban tosilate hydrate

Brand name (marketing authorization holder)

Lixiana Tablets 15 mg, 30 mg, 60 mg, Lixiana OD Tablets 15 mg, 30 mg, 60 mg (Daiichi Sankyo Co., Ltd.)

Japanese market launch

Lixiana Tablets 15 mg, 30 mg: July 2011

Lixiana Tablets 60 mg: December 2014

Lixiana OD Tablets 15 mg, 30 mg, 60 mg: November 2017

Indications

<Lixiana Tablets 15 mg, 30 mg, Lixiana OD Tablets 15 mg, 30 mg>

•Prevention of ischaemic stroke and systemic embolism in patients with non-valvular atrial fibrillation

•Treatment and prevention of the relapse of venous thromboembolism (deep vein thrombosis and pulmonary thromboembolism)

•Prevention of venous thromboembolism in patients undergoing any of the following orthopedic surgeries for the lower limbs:

Total knee replacement, total hip replacement, and hip fracture surgery

<Lixiana Tablets 60 mg, Lixiana OD Tablets 60 mg>

•Prevention of ischaemic stroke and systemic embolism in patients with non-valvular atrial fibrillation

•Treatment and prevention of the relapse of venous thromboembolism (deep vein thrombosis

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and pulmonary thromboembolism)

Summary of revisions

"Thrombocytopenia" 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 thrombocytopenia were evaluated. Cases for which a causal relationship between edoxaban tosilate hydrate and thrombocytopenia 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 thrombocytopenia reported in Japan

A total of 29 cases have been reported to date (including 6 cases for which a causal relationship between the drug and the event was reasonably possible).

A total of 2 patient mortalities have been reported to date. (A causal relationship between the drug and the death subsequent to the event could not be established for any of these cases.)

*Cases were retrieved by MedDRA ver.27.0 SMQ "Haematopoietic thrombocytopenia (narrow)" from the cases collected in the PMDA's database for adverse drug reactions, etc. reports. Among them, cases where the lowest value of the platelet count after the onset of thrombocytopenia fell under grade 3 or higher by Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 were retrieved. Cases without descriptions of platelet count before the onset of thrombocytopenia were excluded.

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).