



Summary of investigation results

Edoxaban tosilate hydrate

January 11, 2018

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 Company, Limited)

Indications

- Reduction of the risk of ischaemic stroke and systemic embolism in patients with non-valvular atrial fibrillation
- Treatment and prophylaxis of the relapse of venous thromboembolism (deep vein thrombosis and pulmonary thromboembolism)
- Reduction of the risk 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

Summary of revision

“Interstitial lung disease” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of interstitial lung disease have been reported in patients treated with edoxaban tosilate hydrate in Japan. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA 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.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 19 cases associated with interstitial lung disease have been reported (including 8 cases for which a causal relationship to the product could not be ruled out). One fatal case has been reported (including 1 case for which a causal relationship to the product could not be ruled out).