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

April 21, 2016

Non-proprietary name

Edoxaban tosilate hydrate

Brand name (Marketing authorization holder)

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

Indications

○ Reduction of the risk of ischemic stroke and systemic embolism in patients with nonvalvular 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

“Hepatic function disorder, jaundice” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of hepatic function disorder and jaundice have been reported in patients treated with edoxaban tosilate hydrate in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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

A total of 5 cases associated with hepatic function disorder have been reported (including 5 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp