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

Apixaban

Non-proprietary name

Apixaban

Brand name (Marketing authorization holder)

Eliquis tablets 2.5 mg, 5 mg (Bristol-Myers Squibb K.K.)

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 embolism).

Summary of revision

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

Background of the revision and investigation results

Cases of hepatic function disorder have been reported in patients treated with apixaban 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.

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

A total of 16 cases associated with hepatic function disorder have been reported (including 5 cases for which a causality to the product could not be ruled out). Of the 16 cases, 1 fatal case has been reported (the causal relationship between the product and the fatal outcome could not be established for this patient).

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