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

Dabigatran etexilate methanesulfonate

September 12, 2017

Non-proprietary name

Dabigatran etexilate methanesulfonate

Brand name (Marketing authorization holder)

Prazaxa Capsules 75 mg, 110 mg (Nippon Boehringer Ingelheim Co., Ltd.)

Indications

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

Summary of revision

“Acute hepatic failure, hepatic function disorder, and jaundice” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of acute hepatic failure, hepatic function disorder, and jaundice have been reported in patients treated with dabigatran etexilate methanesulfonate 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 (since FY 2014)

A total of 5 cases associated with acute hepatic failure, hepatic function disorder, and jaundice have been reported (including one case for which a causal relationship to the product could not be ruled out). One fatal case has been reported (including 0 case for which a causal relationship to the product could not be ruled out).

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