



Summary of investigation results

Rivaroxaban

April 21, 2016

Non-proprietary name

Rivaroxaban

Brand name (Marketing authorization holder)

Xarelto Tablets 10 mg, 15 mg, Xarelto Fine Granules 10 mg, 15 mg (Bayer Yakuhin, 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 deep vein thrombosis and pulmonary thromboembolism

Summary of revision

“Thrombocytopenia” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of thrombocytopenia have been reported in patients treated with rivaroxaban 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 15 cases associated with thrombocytopenia have been reported (including 7 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.