



Summary of investigation results

Apixaban

February 17, 2015

Non-proprietary Name

apixaban

Brand Name (Marketing Authorization Holder)

Eliquis Tablets 2.5 mg and 5 mg (Bristol-Myers K.K.)

Indications

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

Summary of revision

'Interstitial lung disease' should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

The MHLW/PMDA discussed the necessity of adding an alert for interstitial lung disease in the Clinically significant adverse reactions section because cases of interstitial lung disease have been reported in patients treated with apixaban in Japan. Cases of haemorrhage including bloody sputum have been reported. Following an investigation based on the opinions of expert advisors and available evidence, together with consideration of the pharmacology of apixaban, the MHLW/PMDA concluded that revision of the package insert was necessary to include information on interstitial lung disease, including cases of suspected interstitial pneumonia.

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

A total of 23 cases of adverse events suggestive of interstitial lung disease have been reported (including 7 cases in which causality could not be ruled out). A total of 6 fatalities have been reported. No causal relationship with apixaban was established in the fatal cases.