Published by Ministry of Health, Labour and Welfare



Translated by Pharmaceuticals and Medical Devices Agency



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

## **Revision of Precautions**

## Apixaban

February 17, 2015

## **Non-proprietary Name**

apixaban

## Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following texts should be added (underlined parts are revised):

Interstitial lung disease:

Interstitial lung disease may occur. Patients should be carefully monitored. If any abnormalities such as cough, bloody sputum, shortness of breath, dyspnoea, pyrexia, and abnormal chest sound are observed, examinations including chest X-ray, chest CT scan, and serum marker test should be performed immediately. If interstitial lung disease is suspected, administration of this drug should be discontinued, and appropriate measures including administration of corticosteroid should be taken.

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