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.