



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

Edoxaban tosilate hydrate

January 11, 2018

Non-proprietary name

Edoxaban tosilate hydrate

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, sometimes accompanied with bloody sputum or pulmonary alveolar hemorrhage. Patients should be carefully monitored. If any abnormalities such as cough, 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 such as administration of corticosteroid should be taken.