



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

Dabigatran etexilate methanesulfonate

September 12, 2017

Non-proprietary name

Dabigatran etexilate methanesulfonate

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Acute hepatic failure, hepatic function disorder, and jaundice:

Acute hepatic failure, hepatic function disorder, and jaundice may occur. Patients should be carefully monitored, and if any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.