

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

November 26, 2025

Therapeutic category

Anticoagulants

Non-proprietary name

Dabigatran etexilate methanesulfonate

Safety measure

PRECAUTIONS should be revised.

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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.

Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Hemorrhage (Haemorrhage of digestive tract, haemorrhage intracranial, etc.)</p> <p>Haemorrhage including haemorrhage of digestive tract and haemorrhage intracranial may occur.</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Hemorrhage (Haemorrhage of digestive tract, haemorrhage intracranial, etc.)</p> <p>Haemorrhage including haemorrhage of digestive tract, haemorrhage intracranial, and <u>splenic haemorrhage leading to splenic rupture</u> may occur.</p>