

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

Rivaroxaban

November 26, 2025

Therapeutic category

Anticoagulants

Non-proprietary name

Rivaroxaban

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Haemorrhage</p> <p>Serious haemorrhage including haemorrhage intracranial, cerebral haemorrhage, haemorrhagic stroke, eye haemorrhage, retinal haemorrhage, rectal haemorrhage, gastrointestinal haemorrhage, melaena, upper gastrointestinal haemorrhage, lower gastrointestinal haemorrhage, gastric ulcer haemorrhage, intraarticular haemorrhage, and muscle haemorrhage with compartment syndrome may occur. Some fatal cases have been reported. If any abnormalities such as serious haemorrhage are observed, administration should be discontinued.</p> <p>Complications associated with haemorrhage including shock, renal failure, dyspnoea, oedema, headache, dizziness, pallor, and feelings of weakness may occur. Chest pain or angina pectoris-like cardiac ischaemia symptoms have occurred as a result of anaemia in some cases.</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Haemorrhage</p> <p>Serious haemorrhage including haemorrhage intracranial, cerebral haemorrhage, haemorrhagic stroke, eye haemorrhage, retinal haemorrhage, rectal haemorrhage, gastrointestinal haemorrhage, melaena, upper gastrointestinal haemorrhage, lower gastrointestinal haemorrhage, gastric ulcer haemorrhage, intraarticular haemorrhage, muscle haemorrhage with compartment syndrome, and <u>splenic haemorrhage leading to splenic rupture</u> may occur. Some fatal cases have been reported. If any abnormalities such as serious haemorrhage are observed, administration should be discontinued.</p> <p>Complications associated with haemorrhage including shock, renal failure, dyspnoea, oedema, headache, dizziness, pallor, and feelings of weakness may occur. Chest pain or angina pectoris-like cardiac ischaemia symptoms have occurred as a result of anaemia in some cases.</p>