

*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

## Edoxaban tosilate hydrate

November 26, 2025

### **Therapeutic category**

Anticoagulants

### **Non-proprietary name**

Edoxaban tosilate hydrate

### **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>Significant haemorrhage affecting various tissues and organs may occur, including haemorrhage of digestive tract, haemorrhage intracranial, haemorrhage intraocular, wound haemorrhage, and retroperitoneal haemorrhage. Some fatal cases have also been reported. If clinically significant haemorrhage occurs or worsens, administration should be discontinued.</p> | <p>11. ADVERSE REACTIONS</p> <p>11.1. Clinically Significant Adverse Reactions</p> <p>Haemorrhage</p> <p>Significant haemorrhage affecting various tissues and organs may occur, including haemorrhage of digestive tract, haemorrhage intracranial, haemorrhage intraocular, wound haemorrhage, retroperitoneal haemorrhage, and <u>splenic haemorrhage leading to splenic rupture</u>. Some fatal cases have also been reported. If clinically significant haemorrhage occurs or worsens, administration should be discontinued.</p> |