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Pharmaceuticals and Medical Devices Agency

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

August 29, 2023

Therapeutic category

Anticoagulants

Non-proprietary name

Dabigatran etexilate methanesulfonate

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS If this drug is retained in the esophagus, oesophageal ulcer or oesophagitis may occur. Patients should be instructed as follows: •This drug should be taken with a sufficient amount (e.g., a full glass) of water to facilitate delivery to the stomach. •If symptoms of oesophageal disease (difficult swallowing or odynophagia, retrosternal pain, severe and persistent heartburn, etc.) occur, the attending physician should be consulted.
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Oesophageal ulcer, oesophagitis
14. PRECAUTIONS CONCERNING USE Precautions Concerning Administration of the Drug This drug should be taken with a sufficient amount (e.g., a full glass) of water to facilitate delivery to the stomach.	14. PRECAUTIONS CONCERNING USE Precautions Concerning Administration of the Drug (deleted)

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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