



# Summary of Investigation Results

## Dabigatran etexilate methanesulfonate

August 29, 2023

### Non-proprietary name

Dabigatran etexilate methanesulfonate

### Brand name (marketing authorization holder)

Prazaxa Capsules 75 mg, 110 mg (Nippon Boehringer Ingelheim Co., Ltd.)

### Japanese market launch

March 2011

### Indications

Reduction in the risk of ischaemic stroke and systemic embolism in patients with non-valvular atrial fibrillation

### Summary of revisions

1. Precautions for the prevention/early detection of oesophageal ulcer and oesophagitis should be included in the IMPORTANT PRECAUTIONS section.
2. "Oesophageal ulcer, oesophagitis" should be added to the Clinically Significant Adverse Reactions section.

### Investigation results and background of the revision

Considering the situation in which cases involving severe\* oesophageal ulcer or oesophagitis have been reported in Japan, these cases were evaluated. Cases for which a causal relationship between dabigatran etexilate methanesulfonate and oesophageal ulcer or oesophagitis was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of

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revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary. In line with this, it was also concluded that it is necessary to include a statement in the IMPORTANT PRECAUTIONS section that this drug should be taken with a sufficient amount (e.g., a full glass) of water to facilitate delivery to the stomach, which is currently listed in the PRECAUTIONS CONCERNING USE section.

**Reference: Number of cases<sup>†</sup> and patient mortalities involving oesophageal ulcer or oesophagitis reported in Japan**

•Oesophageal ulcer

A total of 17 cases have been reported to date. (A causal relationship between the drug and event was reasonably possible for 14 cases, including 1 case which fell under the contraindications.)

No patient mortalities have been reported to date.

•Oesophagitis

A total of 32 cases have been reported to date. (A causal relationship between the drug and event was reasonably possible for 11 cases, including 1 case which fell under the contraindications.)

No patient mortalities have been reported to date.

\*Cases of grade 3 or higher by the Common Terminology Criteria for Adverse Events (CTCAE v5.0) were evaluated.

<sup>†</sup> Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc.", by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).