This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Warfarin potassium

August 3, 2017

Non-proprietary name

Warfarin potassium

Brand name (Marketing authorization holder)

Warfarin Tablets 0.5 mg, 1 mg, 5 mg, Warfarin Granules 0.2% (Eisai Co., Ltd.), and the others

Indications

Treatment and prevention of thromboembolism (including venous thrombosis, myocardial infarction, pulmonary embolism, brain embolism, and slowly progressive cerebral thrombosis)

Summary of revision

"Calciphylaxis" should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of calciphylaxis have been reported in patients treated with warfarin potassium both in Japan and overseas,* and the United States and European package inserts have been revised. Following investigation results based on the opinions of the expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 11 cases associated with calciphylaxis have been reported (including no cases for which a causal relationship to the product could not be ruled out). One fatal case has been

reported (including no case for which a causal relationship to the product could not be ruled out).

NOTE:

* Gordon H. Bae et al., Am J Med. 128(2015)e19-e21, Al-Ani M et al., BMJ Case Rep.(2016)1-2, etc.