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Eisai Co., Ltd.

EISAI ANNOUNCES JAPAN LAUNCH OF ORAL ANTICOAGULANT WARFARIN GRANULES 0.2%

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today that it will launch Warfarin Granules 0.2%, a new formulation of the company's oral anti-coagulant Warfarin (warfarin potassium), on December 1 in Japan.

Warfarin Granules 0.2% received marketing authorization in Japan on July 15 of this year and was subsequently listed on Japan's National Health Insurance (NHI) drug price list on November 28. This new formulation is designed to help patients who find it difficult to swallow tablets. It also provides healthcare professionals with the ability to easily micro-adjust the dosage of the medication in accordance with the condition and needs of the patient.

Warfarin is an oral anticoagulant that is used to treat a wide range of indications, with its efficacy having been verified in large-scale overseas clinical studies. The agent is widely prescribed to patients as it is recommended as the standard first-line therapy in the treatment and prevention of thromboembolism such as cardiogenic brain embolism and venous thrombosis in treatment guidelines in Japan, the United States and Europe. However, it is also known to have a narrow therapeutic range and interact with other drugs, making it necessary to adjust dosage accordingly through the monitoring of blood clotting ability by measuring prothrombin time, etc.

Able to be administered to patients who find it difficult to take tablets, such as children or those patients who have trouble swallowing, Warfarin Granules 0.2% allows the ingredient warfarin potassium to be precisely adjusted to less than 0.5 mg, and has been triturated 500-fold to ensure appropriate dose-volume. Furthermore, as light causes warfarin potassium to break down, this new granule formulation has been designed with enhanced photostability, which was achieved by applying a coating to the granules and other measures.

Eisai estimates that there are approximately one million patients currently taking Warfarin in Japan. With the addition of the new granule formulation to its existing line up of Warfarin products, which comprises Warfarin Tablets 0.5 mg, 1 mg and 5 mg, Eisai seeks to make contributions to increase the benefits provided to an ever-greater number of patients.

[Please refer to the following notes for a product outline]

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[Notes to editors]

1. Warfarin Product Outline (The underlined parts indicate the new formulation)

1) Product Name

Warfarin Tablets 0.5mg, Warfarin Tablets 1 mg, Warfarin Tablets 5 mg, Warfarin Granules 0.2%

2) Indications

Treatment and prevention of thromboembolism (venous thrombosis, myocardial infarction, pulmonary embolism, cerebral embolism, slowly progressing cerebral thrombosis, etc.)

3) Dosage and Administration

The prothrombin time, measured by Quick's one-stage method, and Thrombotest values are used to control dosage and dosing intervals.

The therapeutic range is approximately twice the normal coagulation time, or 15 to 30% of normal prothrombin activity for the prothrombin time and approximately 10% for the Thrombotest, in many cases.

The initial adult dosage for oral use is 20 to 40 mg of warfarin potassium. The drug is then withdrawn for one or two days until it has been confirmed that coagulation levels are within the therapeutic range, and then the treatment is resumed at a daily maintenance dose of 1 to 5 mg. Alternatively, warfarin potassium is administered orally at a daily dose of 5 to 6 mg for several days until coagulation levels are within the therapeutic range and then the dose is adjusted to the maintenance level.

There are marked individual variations in sensitivity to warfarin potassium and even in the same patient, varying degrees of sensitivity may be observed. The prothrombin time should be measured and the Thrombotest conducted frequently, especially during the early stage of therapy to ensure that coagulation levels remains within the therapeutic range.

In order to accelerate the anticoagulant effect, heparin may be coadministered with the first dose of warfarin potassium.

Maintenance doses in pediatric use are shown below.

<12 months: 0.16 mg/kg/day

1 year old≤ <15 years old: 0.04 to 0.10 mg/kg/day

4) National Health Insurance Drug Price Standard

Product	Specifications	Price (yen)
Warfarin Tablets 0.5 mg	0.5 mg 1 Tablet	9.60
Warfarin Tablets 1 mg	1 mg 1 Tablet	9.60
Warfarin Tablets 5 mg	5 mg 1 Tablet	10.60
Warfarin Granules 0.2%	0.2% 1 g	10.00

5) Packaging

Warfarin Tablets 0.5 mg:

100 Tablets (Blister Packaging/Loose), 500 Tablets (Loose), 1000 Tablets (Blister Packaging)

Warfarin Tablets 1 mg:

100 Tablets (Blister Packaging/Loose), 500 Tablets (Loose), 1000 Tablets (Blister Packaging)

Warfarin Tablets 5 mg

100 Tablets (Loose)

Warfarin Granules 0.2%: 100g

[Product Photograph]