For Immediate Release

December 5, 2018
Sawai Pharmaceutical Co., Ltd.

MHLW Approves New Indication for RISEDRONATE Tablets and DOBUTAMINE I.V. Infusion

Osaka, Japan – December 5, 2018 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) today received approval of partial change applications by the Ministry of Health, Labour and Welfare (MHLW) for RISEDRONATE SODIUM Tablets 17.5 mg [SAWAI]* and DOBUTAMINE HYDROCHLORIDE I.V. Infusion 100 mg [SAWAI]**.

This approval expands the indication of RISEDRONATE SODIUM Tablets 17.5 mg [SAWAI] and DOBUTAMINE HYDROCHLORIDE I.V. Infusion 100 mg [SAWAI] to include the same uses as their brand equivalents.

* Brand products: Actonel® Tablets 17.5 mg and Benet® Tablets 17.5 mg
** Brand products: Dobutrex® I.V. Infusion 100 mg

"Indications and Usage" and "Dosage and Administration" after approvals are listed below;

(1) RISEDRONATE SODIUM Tablets 17.5 mg [SAWAI]

Indications and Usage (New approval is underlined)	Osteoporosis, <u>Paget's disease of bone</u>
Dosage and Administration (New approval is underlined)	Osteoporosis In general, for adults, 17.5 mg of risedoronate sodium to be taken orally once a week upon awakening with an adequate amount of water (about 180 mL). It is recommended that patients do not lie down for at least 30 minutes after taking the medication and should avoid eating, drinking except for water and taking any other oral drugs. <u>Paget's disease of bone</u> <u>In general, for adults, 17.5 mg of risedronate sodium to be taken orally once daily upon awakening with an adequate amount of water (about 180 mL) consecutively for eight weeks. It is recommended that patients do not lie down for at least 30 minutes after taking the medication and should avoid eating, drinking except for water and taking any other oral drugs.</u>

(2) DOBUTAMINE HYDROCHLORIDE I.V. Infusion 100 mg [SAWAI]

Indications and Usage (New approval is underlined)	1. Increasing myocardial contractility in acute circulatory failure 2. Conducting stress echocardiography
Dosage and Administration (New approval is underlined)	1. Increasing myocardial contractility in acute circulatory failure Dobutamine is diluted with 5 % glucose solution or isotonic sodium chloride solution (JP) before use. In general, 1-5 μg/kg/min as dobutamine is administered by intravenous drip infusion. Dobutamine may be adjusted according to the patient's symptoms, and if necessary, it can be increased to 20 μg/kg/min. 2. Conducting stress echocardiography In general, start with 5 μg/kg/min as dobutamine administered by intravenous drip infusion, and increase every 3 minutes to 10, 20, 30, 40 μg/kg/min until a diagnostic endpoint is reached.

◆ Contact information ◆
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