



**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 approval 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 risedronate 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. <u>Conducting stress echocardiography</u>
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. <u>Conducting Stress echocardiography</u> <u>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.</u>

About Sawai

Founded in 1929, Sawai Pharmaceutical Co., Ltd. has grown into one of the leading generics companies in Japan. Guided by its corporate philosophy, "Always Putting Patients First," Sawai markets more than 700 high-quality generic products and reliably delivers them to patients throughout Japan. In 2017, Sawai acquired US-based Upsher-Smith Laboratories, LLC marking its first step in overseas expansion to become a globally recognized generic pharmaceutical company. For more information, visit: <https://www.sawai.co.jp/en/>.

The products announced in this press release are not approved by the Food & Drug Administration for sale and distribution in the United States.

For further information please contact:

PR/IR group, pr@sawai.co.jp