



## MHLW Approves New Indication for PRAMIPEXOLE HYDROCHLORIDE Tablets 0.125mg “SAWAI” / 0.5mg “SAWAI”

Osaka, Japan – March 20, 2018 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) today received approval of a partial change application by the Ministry of Health, Labour and Welfare (MHLW) for PRAMIPEXOLE HYDROCHLORIDE Tablets 0.125mg “SAWAI” / 0.5mg “SAWAI”.

This approval expands the indication of PRAMIPEXOLE HYDROCHLORIDE Tablets 0.125mg “SAWAI” / 0.5mg “SAWAI” to include the same uses as their brand equivalents.

\*Brand products: BI·Sifrol® Tablets 0.125mg / 0.5mg

“Indications and Usage” and “Dosage and Administration” after approval are listed below:

<b>Indications and Usage (New approval is underlined)</b>	1. Parkinson’s Disease (PD) <u>2. Mild to moderate Restless Legs Syndrome (RLS)</u>
<b>Dosage and Administration (New approval is underlined)</b>	1. Parkinson’s Disease (PD) In general, for adults, start with 0.25mg of pramipexole hydrochloride hydrate daily for the first week, and increase to 0.5mg daily for the second week. Thereafter increase the daily dose by an increment of 0.5mg at weekly intervals by checking your condition and determine your maintenance dose [standard daily dose: 1.5-4.5mg]. If the daily dose is less than 1.5mg, divide it into two doses and take each dose after breakfast and dinner. If the daily dose is 1.5mg or more, divide it into three doses and take each dose after each meal. The dosage may be adjusted according to your age and the severity of symptoms, but the maximum daily dose should not exceed 4.5mg. <u>2. Mild to moderate Restless Legs Syndrome (RLS)</u> <u>In general, for adults, start with 0.25mg of pramipexole hydrochloride hydrate two to three hours before bedtime. Increase the daily dose by an increment of 0.125mg at weekly intervals by checking your condition and determine your maintenance dose. The maximum daily dose should not exceed 0.75mg.</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, "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/>.

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