



## MHLW Approves New Indication for OLANZAPINE Formulation\* and New Administration for MEROPENEM Formulation\*\*

Osaka, Japan –April 4, 2018 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) today received approval of two partial change applications by the Ministry of Health, Labour and Welfare (MHLW) for OLANZAPINE Tablets 2.5mg “SAWAI”, 5mg “SAWAI”, 10mg “SAWAI” and Fine Granules 1% “SAWAI” and MEROPENEM I.V. Drip Infusion 0.25g “SAWAI” and 0.5g “SAWAI”.

This approval expands the indication of OLANZAPINE Tablets 2.5mg “SAWAI”, 5mg “SAWAI”, 10mg “SAWAI”, Fine Granules 1% “SAWAI” to include the same uses as their brand equivalents.

\*Brand products: Zyprexa® Tablets 2.5mg, 5mg, 10mg and Fine Granules 1%

\*\*Brand products: MEROPEN® For Intravenous Drip Infusion Vial 0.25g, Vial 0.5g and Kit 0.5g

“Indications and Usage” and “Dosage and Administration” after approvals are as below;

(1) OLANZAPINE Tablets 2.5mg “SAWAI”, 5mg “SAWAI”, 10mg “SAWAI” and Fine Granules 1% “SAWAI”

<b>Indications and Usage (New approval is underlined)</b>	Schizophrenia Treatment of manic and depressive symptoms in bipolar disorder <u>Gastrointestinal symptoms (nausea and vomiting) associated with chemotherapy medicine (such as cisplatin) for cancer</u>
<b>Dosage and Administration (New approval is underlined)</b>	Schizophrenia : In general, for adults, start taking 5 to 10mg of olanzapine at a time, once a day. The dosage is maintained on 10mg once a day, it may be adjusted according to your age and symptoms. However, the daily dosage should not exceed 20mg. Treatment of manic symptoms in bipolar disorder : In general, for adults, start taking 10mg of olanzapine at a time, once a day. The maintenance dosage may be adjusted according to your age and symptoms. However, the daily dosage should not exceed 20mg. Treatment of depressive symptoms in bipolar disorder : In general, for adults, start taking 5mg of olanzapine at a time once a day, and then increase to 10mg once a day. In either case, take before bedtime. The dosage may be adjusted according to your age

	<p>and symptoms. However, the daily dosage should not exceed 20mg. <u>Gastrointestinal symptoms (nausea and vomiting) associated with chemotherapy medicine (such as cisplatin) for cancer:</u></p> <p><u>In general, for adults, take 5mg of olanzapine at a time, once a day in combination with other antiemetics. The dosage may be increased according to your condition. However, the daily dosage should not exceed 10mg.</u></p>
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(2) MEROPENEM I.V. Drip Infusion 0.25g "SAWAI" and 0.5g "SAWAI"

<p><b>Dosage and Administration</b> <b>(New approval is underlined)</b></p>	<p>When using this drug, judge whether further administration is necessary around the 3rd day after the start of administration, and consider whether to stop administration or switch to other, more appropriate drugs.</p> <p>1. Conventional infection</p> <ul style="list-style-type: none"> <li>• Conventional infection except for purulent meningitis</li> </ul> <p>In general, for adults, divide a daily dose of 0.5 to 1 g (potency) of meropenem into two to three times and intravenously infuse taking 30 minutes or longer. The dosage should be adjusted according to the patient's age and symptoms and can be increased to 3g (potency) per day with a ceiling of 1g (potency) per time in patients with severe / refractory infection.</p> <p>In general, for children, divide a daily dose of 30 to 60 mg (potency)/kg of meropenem into three times and intravenously infuse taking 30 minutes or longer. The dosage should be adjusted according to the age and symptoms and can be increased to 120mg (potency)/kg per day in children with severe / refractory infection. However, the dosage should not exceed the maximum daily dose of 3g (potency) for adults.</p> <ul style="list-style-type: none"> <li>• <u>Purulent meningitis</u></li> </ul> <p><u>In general, for adults, divide a daily dose of 6g (potency)/kg of meropenem into three times and intravenously infuse taking 30 minutes or longer. The dosage should be adjusted according to the age and symptoms.</u></p> <p><u>In general, for children, divide a daily dose of 120mg (potency)/kg of meropenem into three times and intravenously infuse taking 30 minutes or longer. The dosage should be adjusted according to the age and symptoms. The dosage should not exceed the maximum daily dose of 6g (potency) per day for adults.</u></p> <p>2. Febrile neutropenia</p> <p>In general, for adults, divide a daily dose of 3g (potency) of</p>
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	<p>meropenem into three times and intravenously infuse taking 30 minutes or longer.</p> <p>In general, for children, divide a daily dose of 120mg (potency)/kg of meropenem into three times and intravenously infuse taking 30 minutes or no longer. The dosage should not exceed the maximum daily dose of 3g (potency) for adults.</p>
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**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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