

For Immediate Release

June 6, 2018
Sawai Pharmaceutical Co., Ltd.

**MHLW approves New Indication
for OSELTAMIVIR Capsules 75mg [SAWAI] / Dry Syrup 3% [SAWAI]**

Osaka, Japan –June 6 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 OSELTAMIVIR Capsules 75mg [SAWAI] and OSELTAMIVIR Dry Syrup 3% [SAWAI]*.

This approval expands the indication of OSELTAMIVIR Capsules 75mg [SAWAI] and OSELTAMIVIR Dry Syrup 3% [SAWAI] to include the same uses as their brand equivalents.

* Brand products: TAMIFLU® Capsules 75mg and Dry Syrup 3%

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

(1) OSELTAMIVIR Capsules 75mg [SAWAI]

Indications and Usage (New approval is underlined)	Treatment <u>or prophylaxis</u> of influenza type A or B virus infection
Dosage and Administration (New approval is underlined)	<p>1. When used for treatment In general, adults and children weighing 37.5 kg or more are orally administered 75 mg as oseltamivir twice a day for 5 days.</p> <p>2. <u>When used for prophylaxis</u></p> <p>(1) <u>Adults</u> <u>In general, 75 mg as oseltamivir is administered orally once a day for 7 to 10 days.</u></p> <p>(2) <u>Children weighing 37.5 kg or more</u> <u>In general, 75 mg as oseltamivir is administered orally once a day for 10 days.</u></p>

(2) OSELTAMIVIR Dry Syrup 3% [SAWAI]

Indications and Usage (New approval is underlined)	<u>Treatment or prophylaxis</u> of influenza type A or B virus infection
Dosage and Administration (New approval is underlined)	<p>1. <u>When used for treatment</u></p> <p>(1) <u>Adults</u> In general, 75 mg as oseltamivir is suspended before use and administered orally twice a day for 5 days.</p> <p>(2) <u>Children</u> In general, the dosage below is suspended before use and administered orally twice a day for 5 days. However, the maximum dose per administration is 75 mg as oseltamivir. Children and young children: 2 mg/kg as oseltamivir (66.7 mg/kg as Dry Syrup) <u>Neonates and infants: 3 mg/kg as oseltamivir (100 mg/kg as Dry Syrup)</u></p> <p>2. <u>When used for prophylaxis</u></p> <p>(1) <u>Adults</u> <u>In general, 75 mg as oseltamivir is suspended before use and administered orally once a day for 7 to 10 days.</u></p> <p>(2) <u>Children</u> <u>In general, the dosage below is suspended before use and administered orally once a day for 10 days. However, the maximum dose per administration is 75 mg as oseltamivir.</u> <u>Children and young children: 2 mg/kg as oseltamivir (66.7 mg/kg as Dry Syrup)</u></p>

◆ Contact information ◆

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