

MHLW Approves Additional Indication for LINEZOLID Injection and Tablets

Osaka, Japan – June 5, 2019 – Sawai Pharmaceutical Co., Ltd. (Head office: Osaka, Japan, President: Mitsuo Sawai) today received approval of partial change applications by the Ministry of Health, Labour and Welfare (MHLW) for LINEZOLID Injection 600 mg [SAWAI] and Tablets 600 mg [SAWAI]*.

This approval expands the indication of LINEZOLID products to include the same uses as their brand equivalents.

* Brand products: ZYVOX® (linezolid) Injection 600 mg and ZYVOX® (linezolid) Tablets 600 mg

“Indications and Usage” and “Dosage and Administration” after approvals are described below (New approval is underlined);

Indications and Usage

1. Indicated bacteria: methicillin-resistant Staphylococcus aureus susceptible to this drug
Indications: sepsis, deep skin infection, chronic pyoderma, secondary infections due to traumatic injury, thermal burn, surgical wound and the like, pneumonia
2. Indicated bacteria: vancomycin-resistant Enterococcus faecium susceptible to this drug
Indications: various types of infectious diseases

Dosage and Administration

◆ LINEZOLID Injection 600 mg [SAWAI]

The usual dose of Linezolid for adults and children 12 years and older is 1200 mg per day, administered as two separate intravenous injections of 600 mg each, every 12 hours. Each injection takes 30 minutes to two hours.

The usual dose of Linezolid for children under 12 years of age is 10 mg/kg at one time, administered by intravenous injection every 8 hours. The dosage should not exceed 600 mg at one time. Each injection takes 30 minutes to two hours.

◆ LINEZOLID Tablets 600 mg [SAWAI]

The usual dose of Linezolid for adults and children 12 years and older is 1200 mg per day, taken orally as two separate tablets of 600 mg each, every 12 hours.

The usual dose of Linezolid for children under 12 years of age is 10 mg/kg at one time, taken orally every 8 hours. The dosage should not exceed 600 mg at one time.

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

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 310 high-quality generic drugs with 760 strengths 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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