

Press Release

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Daiichi Sankyo Announces Launch of Narurapid[®] Tablets and Narusus[®] Tablets for Cancer Pain Treatment

Tokyo, Japan (June 19, 2017) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has launched Narurapid[®] Tablets 1 mg, 2 mg, 4 mg (immediate release formulation) and Narusus[®] Tablets 2 mg, 6 mg, 12 mg, 24 mg (once daily extended release formulation) for cancer pain treatment (generic name: hydromorphone hydrochloride).

Hydromorphone hydrochloride is an opiate, narcotic analgesic that has been available outside of Japan for over 80 years, and is the standard drug for the treatment of cancer pain according to WHO guidelines.

Hydromorphone hydrochloride is one of the agents publicly offered for development by the Review Committee on Unapproved Drugs and Indications with High Medical Needs*. Daiichi Sankyo decided to develop the drug in 2012, and received a grant from the Pharmaceutical Development Support Center for its development.

Daiichi Sankyo is committed to making unapproved and off-label drugs with high medical needs available to the patients who are waiting for them to be approved.

* Working group held by the MHLW that aims to promote the development of drugs and indications not yet approved in Japan, but currently available in Europe and the U.S.

Product name	Narurapid [®] Tablets 1 mg, 2 mg, 4 mg (immediate release formulation)
Generic name(JAN)	Hydromorphone hydrochloride
Price	Narurapid [®] Tablets 1 mg: 110.60 yen/tablet Narurapid [®] Tablets 2 mg: 202.80 yen/tablet Narurapid [®] Tablets 4 mg: 371.90 yen/tablet (Date of listing in the NHI reimbursement price list in Japan: May 24, 2017)
Indication	Analgesic for moderate to severe cancer pain
Dosage and administration	For adults under normal conditions, 4-24 mg of hydromorphone is taken orally 4-6 times a day. Adjust dosage according to symptoms.
Approved for manufacture and marketing	March 30, 2017
Manufacture and marketing	Daiichi Sankyo Propharma Co., Ltd.
Marketing	Daiichi Sankyo Co., Ltd.

Launch date: June 19, 2017

Product name	Narusus [®] Tablets 2 mg, 6 mg, 12 mg, 24 mg (once daily extended release formulation)
Generic name (JAN)	Hydromorphone hydrochloride
Price	Narusus [®] Tablets 2 mg: 202.80 yen/tablet Narusus [®] Tablets 6 mg: 530.20 yen/tablet Narusus [®] Tablets 12 mg: 972.20 yen/tablet Narusus [®] Tablets 24 mg: 1,782.80 yen/tablet (Date of listing in the NHI reimbursement price list in Japan: May 24, 2017)
Indication	Analgesic for moderate to severe cancer pain
Dosage and administration	For adults under normal conditions, 4-24 mg of hydromorphone is taken orally once a day. Adjust dosage according to symptoms.
Approved for manufacture and marketing	March 30, 2017
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Marketing	Daiichi Sankyo Co., Ltd.

About Daiichi Sankyo Opioid Analgesics

Daiichi Sankyo contributes to the total care for the life of patients with cancer by providing opioid analgesics. In addition to Narurapid[®] Tablets (immediate release formulation) and Narusus[®] Tablets (once daily extended release formulation), Daiichi Sankyo has filed an application for a hydromorphone hydrochloride injection in Japan. Daiichi Sankyo launched oxycodone extended release tablets "Daiichi Sankyo" for sustained cancer pain treatment in March 2017 and has received approval for oxycodone immediate release tablets in Japan. Daiichi Sankyo believes that expanding our product lineup of opioid analgesics helps patients with cancer to improve their quality of life by relieving pain and supports patients living with cancer.