

Not intended for US media

15 February, 2021
Okayama Taiho Pharmaceutical Co., Ltd.
Helsinn Group

Announcement of Approval to Manufacture and Market 5-HT₃ (serotonin) receptor antagonist antiemetic agent

「Palonosetron I.V. Injection」, 「Palonosetron I.V. Infusion Bag」 in Japan

Okayama Taiho Pharmaceutical Co., Ltd. (hereafter “Okayama Taiho”, located in Bizen-city, Okayama, Japan, President: Minenobu Katayama) and Helsinn Group (“Helsinn”), a Swiss pharmaceutical group focused on building quality cancer care and rare diseases products, today announce Okayama Taiho has received the approval from the Japanese Ministry of Health, Labour and Welfare to manufacture and market 5-HT₃ (serotonin) receptor antagonist antiemetic agent, Palonosetron I.V. injection 0.75mg/5mL 「TAIHO」 and Palonosetron I.V. infusion bag 0.75mg/50mL 「TAIHO」.

This product, licensed by Helsinn Healthcare SA to Okayama Taiho, is an authorized generic which has an identical formula, API, excipients, manufacturing process, facility, packaging materials, packaged pieces of the box, package size, except product name and package design, to the ALOXI® I.V. injection 0.75mg and I.V. infusion bag 0.75mg of which the MAH is Okayama Taiho’s affiliate Taiho Pharmaceutical Co., Ltd. (hereafter “Taiho”, Located in Chiyoda-ku, Tokyo, Japan, President: Masayuki Kobayashi).

Okayama Taiho will collaborate with Taiho to further contribute to patients and health care professionals.

Product Information

【Product name】	Palonosetron I.V. injection 0.75mg/5mL 「TAIHO」 Palonosetron I.V. infusion bag 0.75mg/50mL 「TAIHO」
【Generic name】	Palonosetron hydrochloride
【Indication】	Digestive symptoms (nausea or vomiting) (including delayed phase) resulting from the administration of antineoplastic agents (cisplatin, etc.)
【Dosage and Administration】	For intravenous and drip infusion use, the usual adult dosage of palonosetron is 0.75 mg per body once daily.
【Package】	Palonosetron I.V. injection 0.75mg/5mL 「TAIHO」 5mL x 5 Vials Palonosetron I.V. infusion bag 0.75mg/50mL 「TAIHO」 50mL x 5 Bags

About Okayama Taiho Pharmaceutical

	Okayama Taiho Pharmaceutical Co., Ltd.
Established	August 1, 1992
Head Office	1775-1 Kugui, Bizen-city, Okayama, Japan
President	Minenobu Katayama
Net sales (2019)	¥4,938M
Employees	172
Business Description	Manufacturing, distributing of pharmaceuticals and other related products
URL	https://www.okayama-taiho.co.jp/

About the Helsinn Group

Helsinn is a privately-owned Swiss Pharma Company which, since 1976, has been improving the lives of patients, guided by core family values of respect, integrity and quality. The Group has an extensive portfolio of marketed innovative cancer and rare disease therapies, a robust drug development pipeline and ambitions to further accelerate its growth through in-licensing and acquisition to address unmet medical needs. Helsinn operates a unique integrated licensing business model, achieving success with long-standing partners in 190 countries, who share our values.

For more information, please visit: <https://www.helsinn.com/about-the-helsinn-group>

The press release has been prepared in compliance with the Japanese regulations.

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