

This material is an English translation of the press release announced on November 28, 2018 in Japanese, and the Japanese release is given priority about the content and the interpretation.

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November 28, 2018

**Notification of listing on the NHI drug price standard and marketing of  
a new dose “0.5 mg” of ‘Fentos® Tape (Development code: HFT-290)’,  
Transdermal, Pain management patch**

Hisamitsu Pharmaceutical Co., Inc. (Head Office: Tosu city, Saga prefecture, Japan; Chairman and CEO: Hirotaka Nakatomi, hereinafter referred to as Hisamitsu) hereby announces that “0.5mg” of ‘Fentos® Tape (development code: HFT-290, hereinafter “this product”)', Transdermal, Pain management patch, for which Hisamitsu received approval for partial changes regarding the addition of a new dosage in July 2018, has been listed on the National Health Insurance (NHI) drug price standard as of today. In addition, the launch of “0.5 mg” of this product is scheduled on December 17, 2018.

Hisamitsu obtained an approval for manufacturing and marketing for this product in April 2010 with an indication for “pain relief in various cancers that accompany with moderate to severe pain” and obtained an additional approval in June 2014 for the indication of “pain relief for moderate to severe chronic pain”.

Hisamitsu expects that the 0.5mg dose of this product in patients with cancer pain and patients with chronic pain enables a more careful dose adjustment at the time of switching from other low dose opioid analgesics and in dose increase or decrease.

Hisamitsu has jointly carried out product distribution, collection and provision of medical information (1 brand, 2 channels) with Kyowa Hakko Kirin Co., Ltd., (Head office: Chiyoda-ku, Tokyo, Japan; President: Masashi Miyamoto; hereinafter referred to as “Kyowa Hakko Kirin”) since June 2010.

Hisamitsu keep co-marketing this product with Kyowa Hakko Kirin, and contribute to improve the quality of life of patients suffering from cancer pain and chronic pain by providing appropriate information.

\* For reference

Trade name	Fentos® Tape 0.5mg, 1mg, 2mg, 4mg, 6mg, 8mg
Active ingredient	Fentanyl citrate
Indications	The following pains that are difficult to treat with non-opioid analgesics or weak opioid analgesics (However, the usage is restricted to cases when this drug is switched from other opioid analgesics). Various cancers that accompany moderate to severe pain Moderate to severe chronic pain
Dosage and administration	This drug should be switched from other opioid analgesics. For adults, this drug is usually applied to regions such as the chest, abdomen, upper arm or thigh and should be replaced with a new patch every day (approximately 24 hours). The initial dosage will be selected from either 0.5 mg, 1 mg, 2 mg, 4 mg or 6mg, taking into consideration the dosage and administration of the previous opioid analgesic just before the application of this drug. The subsequent dosage should be adjusted according to the patient's symptoms and condition.

Information on Fentos® Tape 0.5 mg is as follows:

Size of preparation	5 cm <sup>2</sup> (1.59cm×3.16cm)
Packaging	7 sheets(1 sheet/1 pack×7 patches)
NHI drug price	303.80 yen/sheet
Date of approval for manufacturing and marketing	July 2, 2018
Date of NHI drug price listing	November 28, 2018
Date of initial marketing in Japan	December 17, 2018 (scheduled date)