

September 25, 2013

Taiho Pharmaceutical Co., Ltd.

Teikoku Seiyaku Co., Ltd.

Cancer Pain Reliever E-fen Buccal Tablets Launched

Taiho Pharmaceutical Co., Ltd. (HQ: Tokyo; President: Masayuki Kobayashi) and Teikoku Seiyaku Co., Ltd. (HQ: Higashi Kagawa, Kagawa Prefecture; President & CEO: Misako Fujioka; hereafter “Teikoku”) announced today, that E-fen buccal tablets (Nonproprietary name: fentanyl citrate, Development code: OVF), a cancer pain reliever for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain, will be launched in Japan on Thursday, September 26.

For the sudden and intense pain (breakthrough pain) sometimes experienced by cancer patients whose continuous cancer pain has been brought under control, E-fen buccal tablets are placed in the buccal area (between the gum of the maxillary molars and the cheek) where the drug is absorbed through the oral mucosa for fast-acting analgesic effect. It is the first rapid-release fentanyl drug in Japan, and it has been approved*¹ in 34 countries around the world, where it is marketed under brand names such as Fentora® (USA) and Effentora® (Europe).

*1: As of April 30, 2013

E-fen buccal tablets were developed in Japan by Taiho Pharmaceutical per a license agreement (2005) between Taiho Pharmaceutical and the U.S. pharmaceutical company Cima Labs Inc. (currently known as Cephalon, Inc.*²). Taiho Pharmaceutical and Teikoku entered into a business partnership in 2012. Teikoku obtained approval to manufacture and market the drug on June 28, 2013 and obtained an NHI price listing for the drug on August 27. Teikoku will handle import and manufacturing and Taiho Pharmaceutical will handle marketing.

*2: Cephalon, Inc. was merged with Teva Pharmaceutical Industries Ltd. in 2011.

Taiho Pharmaceutical and Teikoku are cooperating to supply appropriate information about the drug to medical professionals and maintain their commitment to make further contributions to patients suffering from cancer pain.

Product Summary	
Brand name	E-fen buccal tablets 50µg, 100µg, 200µg, 400µg, 600µg, 800µg
Nonproprietary name	Fentanyl citrate
Indications & Efficacy	For the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain
Use & Dosage	<p>Normally, adults whose initial dosage is 50µg or 100µg of E-fen per each breakthrough pain episode are to place the E-fen tablet between the cheek and gum above a molar tooth to allow for dissolution.</p> <p>During titration, the dosage of E-fen may be increased in order in steps of 50µg, 100µg, 200µg, 400µg, 600µg, and 800µg per dosage in accordance with symptoms until the optimal dosage is determined. If, during titration, the breakthrough pain episode is not relieved after 30 minutes for a single dosage of 50µg up to 600µg, patients may take only one additional dose up to the same strength for that episode.</p> <p>Once titrated to an effective dose, patients should generally use only one F-fen tablet of the appropriate strength per breakthrough pain episode.</p> <p>The maximum dosage per administration of E-fen is 800µg.</p> <p>Except for an additional dosage during titration, patients must wait at least 4 hours before treating another episode of breakthrough pain with E-fen. The drug may be administered no more than four times per day per breakthrough pain episode.</p>
Date of manufacturing and marketing approval	June 28, 2013
Date listed in NHI reimbursement price listing	August 27, 2013
Date of initial marketing in Japan	September 26, 2013
NHI reimbursement price	E-fen Buccal tablets 50 µg: 507.50 yen/tablet E-fen Buccal tablets 100 µg: 708.10 yen/tablet E-fen Buccal tablets 200 µg: 988.00 yen/tablet E-fen Buccal tablets 400 µg: 1,378.60 yen/tablet E-fen Buccal tablets 600 µg: 1,675.20 yen/tablet E-fen Buccal tablets 800 µg: 1,923.60 yen/tablet
Marketing	Taiho Pharmaceutical Co., Ltd.
Manufacturing distributor	Teikoku Seiyaku Co., Ltd.