



## Therapeutic Class Review<sup>SM</sup>

### Pain – fentanyl buccal tablet (Fentora<sup>®</sup>)

February 2007

#### New Product for Review:

Fentanyl buccal tablet (Fentora<sup>®</sup>)  
[Cephalon]

#### Dossier Provided by Manufacturer:

##### Dossier Evaluation: (2)

- 1- dossier w/missing components
- 2- all components present, except pharmacoeconomic model
- 3- all components present (comprehensive)

#### Executive Summary

- Fentanyl buccal tablet (Fentora) is a potent opioid analgesic indicated specifically in patients with cancer breakthrough pain (BTP).
  - Fentanyl is approximately 80 times more potent than morphine.
- Fentanyl buccal tablet (Fentora):
  - Is similar in action to other narcotic analgesic medications in relieving pain.
  - Contains the same medication as oral transmucosal fentanyl citrate (OTFC) [Actiq<sup>®</sup>] which is now available generically.
- Like other narcotic analgesics, fentanyl buccal tablet (Fentora) has a Black Box Warning to emphasize the potential for accidental overdose, misuse, abuse and diversion.
- There are significant safety concerns with fentanyl buccal tablet (Fentora).
  - Due to life threatening respiratory depression, Fentora is contraindicated in:
    - Non-opioid tolerant patients.
    - Management of acute or postoperative pain.
  - Fentora mcg  $\neq$  Actiq mcg
    - Fentanyl buccal tablet (Fentora) provides a higher bioavailability of fentanyl than OTFC (Actiq).
    - Cannot substitute on a mcg per mcg basis.
- There is a risk for over utilization, off-label and inappropriate use with fentanyl buccal tablet (Fentora) in non-cancer pain conditions.

#### Evidence

- There is no useful evidence supporting the efficacy of fentanyl buccal tablet (Fentora) in the treatment of breakthrough pain.
- Large patient drop-outs and final results that are not based on all randomized patients (lack of an intent-to-treat analysis) make these trials unreliable in making healthcare decisions.

### Decision

- Fentanyl buccal tablet (Fentora) is non-preferred/non-formulary because:
  - There is no useful evidence of improved efficacy over existing formulary agents.
  - This product is approved for limited indications, and there are safety concerns around dosing.
  - This product has a higher cost relative to other formulary agents, yet adds no extra benefit.

### Products

Drug Products	FDA approval <sup>a</sup>	FDA approved indications	Usual Dose/Route	Potential Off-label Uses <sup>c</sup>
fentanyl buccal tablet (Fentora)	9/2006	Breakthrough cancer pain	200-800mcg orally qd-qid prn	Non-cancer pain
oral transmucosal fentanyl citrate (OTFC) (generic)	11/1998	Breakthrough cancer pain	200-1600mcg orally qd-qid prn	Non-cancer pain
hydromorphone tablet (generic) [various]	1/1984	Management of moderate to severe pain	2-4 mg orally every)	cough
levorphanol tablet (generic) [various]	1/1953	Management of pain when an opioid analgesic is appropriate	2-4 mg orally every 6 to 8 hours (chronic)	none
methadone tablet (generic) [various]	8/1947	(1) Severe pain (2) Detoxification and treatment of narcotic addiction	2.5 to 10 mg orally every 3 to 4 hours (chronic)	restless leg syndrome
morphine sulfate tablet (generic) [various]	not available	For relief of moderate to severe pain	15-30 mg orally every 3 to 4 hours (chronic)	secretory diarrhea
oxycodone tablet (generic) [various]	2/2004	For relief of moderate to moderately-severe pain	5-30 mg orally every 4 to 6 hours	secretory diarrhea, restless leg syndrome

<sup>a</sup> Date applies to approval date for the original brand name medication where there are now generics available.

<sup>c</sup> As listed in © 1974 - 2006 Thomson MICROMEDEX database or as referenced.

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