

Fentora™ (fentanyl buccal tablet)

Important Notice

BACKGROUND

Fentora™ is a quick-onset, short-acting, opioid (narcotic) medication that has been on the market for approximately one year and contains the same active ingredient as Actiq™. Fentora was approved by the Food and Drug Administration (FDA) for the treatment of breakthrough pain in patients with cancer who are already receiving and are tolerant to opioid therapy for underlying persistent cancer pain.

Prescription records from several large workers' compensation payors show that fentanyl citrate products, Fentora and Actiq, are the number six drugs, by cost.

NEW DEVELOPMENTS

On **September 10, 2007**, Cephalon, the makers of Fentora, issued a "Dear Healthcare Professional" letter due to the recent reports of four deaths related to the drug. All four deaths were related to improper patient selection, dosage, or product substitution.

One of the deaths involved a person committing suicide while on the medication, although it was not prescribed to him. The other three deaths appear to be from respiratory depression due to inappropriate prescribing. Two of the patients were prescribed the medication for headaches. The patients were not on around-the-clock opiates. The fourth death occurred because the patient was prescribed a dose outside of the recommendations.

None of the patients who died were using the medication to treat cancer pain, which is Fentora's **only** FDA-approved indication. No other information about the deaths has been reported; however, the FDA is currently monitoring the situation.

Prescribers do not have to confine their prescribing habits to only those conditions approved by the FDA. Pharmaceutical manufacturers, however, are not permitted to actively promote the use of their products for any unapproved purposes. Cephalon is currently being investigated by various regulatory agencies, including Congress, for accusations of marketing Fentora outside of its indications. The company has denied all claims. Obviously, the vast majority of prescriptions for fentanyl citrate products within the workers' compensation industry are for "off-label" or unapproved pain indications.

PLACE IN WORKERS' COMPENSATION

Prescription records from several large workers' compensation payors show that fentanyl citrate products, Fentora and Actiq, are the number six drugs, by cost. Fentora prescriptions are responsible for 25% of fentanyl citrate prescriptions dispensed. While Fentora contains the same active ingredient as Actiq, more of the medication is absorbed into the body via a Fentora tablet. This makes Fentora more potent than Actiq and thus, lower doses of Fentora are required.

The manufacturer recommends the following to reduce the risk of a patient experiencing an overdose of Fentora:

Fentora should **ONLY** be used:

- In opioid-tolerant patients (patients taking around-the-clock opioids). In order for a patient to be considered opioid tolerant, they must be on at least one of the following drugs for at least one week: 60mg oral morphine/day, 25mcg fentanyl patch/hr, 30mg oral oxycodone/day, 8mg oral hydromorphone/day, or an equianalgesic dose of another opioid.
- For labeled indications, which is breakthrough pain in opioid-tolerant patients with cancer.

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Fentora should NOT:

- Be prescribed for patients with acute pain, post-operative pain, headache/migraine, or sports injuries.
- Be substituted for other fentanyl products, such as Actiq. The doses are not equivalent. Table 7 of Fentora's package insert lists the dosing conversion recommendations for converting Actiq to Fentora.

Patients should NOT:

- Take more than two tablets of Fentora per breakthrough pain episode, and must wait at least four hours before treating another episode. If pain is still persisting, the dosage may need to be titrated upwards to provide adequate pain relief.

While it is unrealistic to assume that this medication will only be used for breakthrough cancer pain within the workers' compensation industry, these recommendations should be considered carefully prior to approving this medication. **This is not an appropriate medication to be used by injured workers who are not tolerant or accustomed to using opioid (narcotic) medication.**

MITIGATING RISKS

All opioid medications carry the risk of overdose. Due to the potency of this medication and the population for which it was initially designed (opioid-tolerant cancer patients), Fentora can be responsible for an accidental overdose even at seemingly "low" doses, if not prescribed appropriately. Prior to the reports of these deaths, these products were primarily monitored within the industry due to their cost.

Clients using PMSI's Arkos™ Risk Management system routinely have their injured workers reviewed for the use of these products. PMSI will continue to monitor developments regarding Fentora and work with our payors to design programs to mitigate the risks associated with it.

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175 Kelsey Lane Tampa, FL 33619 PH: 877.ASK.PMSI www.pmsionline.com

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