This Fast Fact does NOT address ACTIQ® (oral transmucosal fentanyl citrate, OTFC)

Fentanyl buccal tablet (FENTORA™) is a flat faced, round, beveled-edge tablet intended for buccal administration. The tablet is placed and retained within the buccal cavity, between the cheek and upper gum above a rear molar tooth, for a period sufficient to allow its disintegration and absorption of fentanyl across the oral mucosa. FENTORA utilizes the OraVent® drug delivery technology, which generates a transient pH change which optimizes dissolution and membrane permeation in the immediate area of the oral mucosa around the drug.

Bioavailability of FENTORA is 65%. Approximately 50% of the total dose administered is absorbed transmucosally and becomes systemically available. The remaining half of the dose is swallowed and undergoes slower absorption from the gastrointestinal tract. FENTORA has been shown to produce an onset of analgesia within 15 minutes in some patients and peak at approximately 35-45 minutes. Duration of pain relief may last for up to 60 minutes after administration.

Prescribing Information:

- This product is NOT intended for use in opioid naïve patients. Patients considered opioid tolerant are those who are taking at least 60 mg of oral morphine/day, 25 mcg/hour of transdermal fentanyl, 30 mg of oxycodone daily, 8 mg of oral hydromorphone/day or an equianalgesic dose of another opioid for a week or longer.
- FENTORA is available in 100, 200, 400, 600 & 800 mcg dosage strengths. FENTORA is sugar-free.
- FENTORA should be started at 100 mcg and titrated upward based on individual patient response.
- When switching patients from ACTIQ or OTFC, use the starting dose as outlined in the Dosing Conversion Table (see above).
- If pain is not adequately relieved within 30 minutes, a second dose of the same dosage strength can be used.
- Multiples of the 100 mcg tablet can be used during titration. Patients needing more than 100 mcg should be instructed to use two 100 mcg tablets (one in the buccal cavity on each side of the mouth). Use 200 mcg increments to titrate above 400 mcg. Four 100 mcg tablets were found to produce approximately 13% higher peak blood levels compared to one 400 mcg tablet. This slight difference will probably not have a clinically meaningful impact on pain relief. Using more than four 100 mcg tablets simultaneously has not been evaluated. It is important to monitor patient response closely and minimize the number of different strengths available to patients at any time to prevent confusion and possible overdose.
- No predictive relationship was seen between the successful dose of FENTORA and the dose of the around-the-clock or rescue medication.
- In all clinical trials of FENTORA, the most common side effects observed were nausea, dizziness, vomiting, fatigue, headache, constipation, and somnolence. Most side effects were mild to
Pain Fast Fact: Fentanyl Buccal Tablet (FENTORA™) continued

moderate in severity and typical of all opioids. Application site reactions tended to occur early in treatment, were self-limited and resulted in treatment discontinuation for 2% of patients.

- The concomitant use of FENTORA with the following drugs may result in potentially dangerous increase in fentanyl plasma levels which may cause respiratory depression:
  - Strong cytochrome P450 (CYP) 34A inhibitors such as ritonavir, ketoconazole, itraconazole, troleandomycin, clarithromycin, nelfinavir, and nefazadone.
  - Moderate CYP 34A inhibitors such as amprenavir, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, grapefruit juice and verapamil.

- As with all opioids, patients should be warned not to combine FENTORA with alcohol, sleep aids, or central nervous system depressants except by the orders of the prescribing physician.

Important Patient Information on Consumption Technique and Storage:

- Patients should be instructed NOT to open the blister package until ready to use; and NOT to push the tablet through the foil on the blister pack since this could damage the tablet. Patients should be instructed NOT to split the tablet.

- Once removed from the blister pack, the patient should immediately place the tablet in the mouth between the cheek and gum above a molar tooth, and allow the tablet to dissolve which may take about 14 to 25 minutes. If remnants of the tablet still remain after 30 minutes, patients may swallow them with a glass of water.

- Patients should be instructed NOT to swallow the tablets whole; this will reduce the effectiveness of the medication.

Patients should be warned to properly store and protect the medicine from theft, m

References: