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## Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results

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**Introduction:** Most patients with chronic pain experience episodes of breakthrough pain (BTP), yet no currently available pharmacologic agent is ideal for its treatment. Fentanyl effervescent buccal tablets (FEBT) are designed to enhance the rate and efficiency of fentanyl absorption through the buccal mucosa, which may provide rapid-onset analgesia appropriate for BTP management. Interim 4-month safety and tolerability results from an ongoing multicenter study of FEBT in opioid-tolerant patients with chronic pain and BTP are presented here. **Methods:** This study received ethical approval at all centers. Eligible patients (18–80 years old) had low back pain, diabetic neuropathy, postherpetic neuralgia, complex regional pain syndrome, trauma, osteoarthritis, or chronic headache, experienced 1–4 episodes of BTP per day, and were receiving around-the-clock opioids. After titration, patients managed episodes of BTP with 100–800 µg of FEBT; vital signs and adverse events (AEs) were monitored monthly. Interim safety data represent the period from March 29, 2005 to July 29, 2005. **Results:** Of 98 enrolled patients, 94 (61% women) were administered ≥1 dose of FEBT; 85 continue on in the open-label phase. The percentage of patients at each dose was 1% at 100 µg, 15% at 200 µg, 16% at 400 µg, 16% at 600 µg, and 41% at 800 µg. Patients experienced an average of 2.5 episodes of BTP daily. Twenty-two patients experienced treatment-related AEs, 1 of which was serious (vomiting, dehydration, and lower abdominal pain); 5 patients experienced application-site AEs (pain, irritation, ulceration, or vesicles). Three patients discontinued because of AEs (rash, application-site-related vesicles, nausea, vomiting, dizziness, and headache). The most common AEs were nausea (7%) and dizziness (5%). **Conclusions:** Interim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP.

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