
Prior Authorization DRUG Guidelines

ACTIQ® (fentanyl lozenge)

Effective Date: 10/27/05

Date Developed: 7/2/5 by C. Wilhelmy MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Actiq is an oral transmucosal preparation of the narcotic analgesic fentanyl citrate.

Pre-Authorization Criteria: treatment of breakthrough cancer pain in patients ≥ 16 years old who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

VCHCP will authorize its use for patients who have failed treatment with oxycodone, oral morphine, oral dilaudid, fentanyl patches, and liquid morphine.

Note: "Opioid-tolerant" patients are defined as patients who are taking at least:

Oral morphine 60 mg/day, **or**

Transdermal fentanyl 25 mcg/hour, **or**

Oral oxycodone 30 mg/day, **or**

Oral hydromorphone 8 mg/day, **or**

Oral oxymorphone 25 mg/day, **or**

Equianalgesic dose of another opioid for at least 1 week

DOSING: ADULTS —initial starting dose of 200 mcgs;. a second dose may be started 15 minutes after completion of the first dose, if needed to satisfactorily relieve pain, then titrated so that the patient's pain can be treated with one single dose. Generally, 1-2 days is required to determine this dose.. Consumption should be limited to 4 units/day or less.

How Supplied: individually wrapped blister pack (30 per carton) in the following microgram doses: 200, 400, 600, 800, 1200 and 1600

PRECAUTIONS —Actiq® should be used only for the care of cancer patients and is intended for use by specialists who are knowledgeable in treating cancer pain. For patients who have received transmucosal product within 6-12 hours, it is recommended that if other narcotics are required, they should be used at starting doses 1/4 to 1/3 those usually recommended. Actiq® preparations contain an amount of medication that can be fatal to children. Safety and efficacy have not been established in children <16 years of age; Do not convert a patient to ACTIQ from any other fentanyl product on a

mcg per mcg basis (there are no safe conversion directions available for patients on any other fentanyl products); Respiratory depression is the chief hazard of fentanyl (as with all opioids).

Drug Interactions: use caution with concomitant use of ACTIQ with other CNS depressants; concomitant use with potent inhibitors of cytochrome P450 3A4 isoform (e.g., erythromycin, ketoconazole, grapefruit and grapefruit juice and certain protease inhibitors) may increase fentanyl levels, resulting in increased depressant effects

REFERENCES

1. Anwar, M, Garrettson, L, Huddleston, K, et al. Withdrawal Seizures in a Neonate Following Prolonged Fentanyl Use. Clin Toxicol 1995; 33:493.
2. Baraka, A. Fentanyl-Induced Laryngospasm Following Tracheal Extubation in a Child. Anaesthesia 1995; 50:375.
3. Bedford, NM, Lockey, DJ. Raynaud's Syndrome Following Intravenous Induction of Anaesthesia. Anaesthesia 1995; 50:248.
4. Bennett, MR, Adams, AP. Postoperative Respiratory Complications of Opiates. Clin Anaesthesiol 1983; 1:41.
5. Billmire, DA, Neale, HW, Gregory, RO. Use of I.V. Fentanyl in the Outpatient Treatment of Pediatric Facial Trauma. J Trauma 1985; 25:1079.
6. Carr, DB, Jacox, AK, Chapman, RC, et al. Acute Pain Management. Guideline Technical Report, No. 1. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. AHCPR Publication No. 95-0034. February 1995.
7. Chaturvedi, AK, Rao, NG, Baird, JR. A Death Due to Self-Administered Fentanyl. J Anal Toxicol 1990; 14:385.
8. Drugs for Pain. Med Lett Drugs Ther 2000; 42:73.
9. Fine, PG. Fentanyl in the Treatment of Cancer Pain. Semin Oncol 1997; 24(5 Suppl 16):16.
10. Furuya, H, Okumura, F. Hemolysis After Administration of High Dose Fentanyl. Anesth Analg 1986; 65:207.
11. Jacobi, J, Fraser, GL, Coursin, DB, et al. Clinical Practice Guidelines for the Sustained Use of Sedatives and Analgesics in the Critically Ill Adult. Crit Care Med 2002; 30(1):119-41. Available at: <http://www.sccm.org/pdf/sedatives.pdf>. Accessed August 2, 2003.
12. Jeal, W, Benfield, P. Transdermal Fentanyl. A Review of Its Pharmacological Properties and Therapeutic Efficacy in Pain Control. Drugs 1997; 53:109.
13. Select Drug Information from Lexi-CompOnline
14. www.uptodate.com Fentanyl Drug Information
15. Epocrates 2013 www.epocrates.com

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