

ONSOLIS (fentanyl buccal soluble film)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Robert Sterling, MD

Last Approval Date: 1/26/16, 01/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

Onsolis is fentanyl delivered via a small (dime-sized) film that is placed on the buccal mucosa. It is used to manage breakthrough pain in adult (>18 y.o.) cancer patients.

Authorization: breakthrough pain relief in opioid tolerant patients

Dosing: 200 mcg, 400mcg, 600mcg, 800 mcg, or 1200 mcg every two hours (maximum) as needed for breakthrough pain (initial dose 200 mcg, then titrate in increments of 200 mcg)

PRECAUTIONS: requires careful titration by provider familiar with the drug and its side effects; somnolence/stupor, respiratory depression, constipation; bradycardia; use with CYP34A inhibitors results in increased clinical effects and side effects; must use exactly as described in the product information

DRUG INTERACTIONS: other opiates/opioids; other soporific medications (benzodiazepines, barbiturates, antihistamines, psychotropics, etc)

NOTE: Only available through the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS program.

Enrollment in the program is required for outpatients, prescribers for outpatient use, pharmacies (inpatient and outpatient), and distributors. Enrollment is not required for inpatient administration (eg, hospitals, hospices, long-term care facilities), inpatients, and prescribers who prescribe to inpatients. Further information is available at 1-866-822-1483 or at www.TIRFREMSaccess.com

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