



ACTIQ may be dispensed only to patients enrolled in the TIRF REMS Access program. The goals of the program are to mitigate the risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors.

Click the button to the right for additional information.

TIRF REMS Access program

ACTIQ is indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Limitations of Use:

ACTIQ may be dispensed only to patients enrolled in the TIRF REMS Access program.

Important Safety Information

ACTIQ® (fentanyl citrate) oral transmucosal lozenge [C-II]

WARNING: RISK OF RESPIRATORY DEPRESSION, MEDICATION ERRORS, ABUSE POTENTIAL

RESPIRATORY DEPRESSION

Fatal respiratory depression has occurred in patients treated with ACTIQ, including following use in opioid non-tolerant patients and improper dosing. The substitution of ACTIQ for any other fentanyl product may result in fatal overdose.

Due to the risk of respiratory depression, ACTIQ is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.

Death has been reported in children who have accidentally ingested ACTIQ. ACTIQ must be kept out of reach of children.

The concomitant use of ACTIQ with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression.

MEDICATION ERRORS

Substantial differences exist in the pharmacokinetic profile of ACTIQ compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in fatal overdose.

- When prescribing, do not convert patients on a mcg per mcg basis from any other fentanyl products to ACTIQ.
- When dispensing, do not substitute an ACTIQ prescription for other fentanyl products.

ABUSE POTENTIAL

ACTIQ contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. ACTIQ can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing ACTIQ in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.

Because of the risk for misuse, abuse, addiction, and overdose, ACTIQ is available only through a restricted program required by the Food and Drug Administration, called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access program, outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the program. Further information is available at www.TIRFREMSAccess.com or by calling 1-866-822-1483.

Indication: ACTIQ is indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

Limitations of Use:

ACTIQ may be dispensed only to patients enrolled in the TIRF REMS Access program.

The following is not a complete list; please see full prescribing information.

Contraindications:

- ACTIQ is contraindicated in opioid non-tolerant patients. Life-threatening respiratory depression and death can occur at any dose in opioid non-tolerant patients
- ACTIQ is contraindicated in the management of acute or postoperative pain including headache/migraines and dental pain
- ACTIQ is contraindicated in patients with known intolerance or hypersensitivity to any of its components or the drug fentanyl

Warnings and Precautions:

- Clinically significant respiratory and CNS depression can occur. Monitor patients accordingly
- ACTIQ is not bioequivalent to other fentanyl products. Do not convert patients on a mcg per mcg basis from other

fentanyl products

- Full and partially consumed ACTIQ units contain a medicine in an amount which can be fatal to a child. Death has been reported in children who have accidentally ingested ACTIQ. Ensure proper storage and disposal. Interim safe storage container available ("[ACTIQ Child Safety Kit](#)")
- Use with other CNS depressants and potent cytochrome P450 3A4 inhibitors may increase depressant effects including respiratory depression, hypotension, and profound sedation. Consider dosage adjustments if warranted
- ACTIQ may impair the ability to drive a car or perform other potentially dangerous tasks. Counsel patients accordingly
- Titrate ACTIQ cautiously in patients with chronic obstructive pulmonary disease or preexisting medical conditions predisposing them to respiratory depression and in patients susceptible to intracranial effects of CO₂ retention
- Use ACTIQ with caution in patients with bradyarrhythmias

Adverse Reactions:

- Most common (frequency ≥5%): nausea, dizziness, somnolence, vomiting, asthenia, and headache, dyspnea, constipation, anxiety, confusion, depression, rash, and insomnia

Drug Interactions:

- The concomitant use of ACTIQ with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations, and may cause potentially fatal respiratory depression
- ACTIQ is not recommended for use in patients who have received MAO inhibitors within 14 days, because severe and unpredictable potentiation by MAO inhibitors has been reported with opioid analgesics

Use in Specific Populations:

- Administer ACTIQ with caution to patients with liver or kidney dysfunction

Please see accompanying full [prescribing information](#), including boxed warning.

ACT-2025 ISI

[Patient Child Safety Kit Request \(English\) »](#)

[Healthcare Professional Child Safety Kit Request »](#)

[Patient Child Safety Kit Request \(Spanish\) »](#)

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