Fentora (fentanyl) - Drug Summary

Cephalon, Inc.

Related Drug Information ▼

Fentora
(fentanyl)

BOXED WARNING

Fatal respiratory depression may occur. Contraindicated in the management of acute or postoperative pain (eg, headache/migraine) and in opioid-nontolerant patients. Keep out of reach of children. Concomitant use with CYP3A4 inhibitors may increase plasma levels, and may cause fatal respiratory depression. Do not convert patients on a mcg-per-mcg basis from any other fentanyl products to Fentora. Do not substitute for any other fentanyl products; may result in fatal overdose. Contains fentanyl with abuse liability similar to other opioid analgesics. Available only through a restricted program called Transmucosal Immediate Release Fentanyl Risk Evaluation Mitigation Strategy (TIRF REMS) Access program due to risk of misuse, abuse, addiction, and overdose. Outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in this program.

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Cancer Pain

Breakthrough Pain:
Initial: 100mcg
Max: 2 doses/episode of breakthrough pain
Titrate:
If higher dose is needed, may give two 100mcg tabs (1 on each side of the mouth) w/ their next breakthrough pain episode
May titrate to two 100mcg tabs on each side of mouth (total of four 100mcg tabs), if pain is not adequately controlled
For doses >400mcg, titrate using multiples of 200mcg tabs
Do not use >4 tabs simultaneously
Maint:
Once titrated to effective dose, use only 1 tab of the appropriate strength per breakthrough pain episode
If breakthrough pain is not relieved after 30 min, may give only 1 additional dose of the same strength for that episode; wait at least 4 hrs before treating another breakthrough pain episode
If >4 episodes/day are experienced, dose of the around-the-clock opioid should be reevaluated

Conversions

Initial Fentora Dose Based on Current Actiq Dose:
200mcg of Actiq: 100mcg
400mcg of Actiq: 100mcg
600mcg of Actiq: 200mcg
800mcg of Actiq: 200mcg
1200mcg of Actiq: 2 x 200mcg tabs
1600mcg of Actiq: 2 x 200mcg tabs

Titrate to effective dose

DOSING CONSIDERATIONS

Discontinuation

Gradual downward titration is recommended

ADMINISTRATION

Buccal/SL route

Do not split, crush, suck, chew, or swallow whole
Do not attempt to push tab through the blister as this may cause damage to the tab
Immediately place entire tab in the buccal cavity (above a rear molar, between the upper cheek and gum)
Once effective dose is determined during titration, an alternate route is SL
Leave tab in place until it has disintegrated (usually about 14-25 min)
If remnants from the tab remain after 30 min, may swallow w/ a glass of water
Alternate sides of the mouth when administering subsequent doses in the buccal cavity

HOW SUPPLIED

Tab, Buccal: 100mcg, 200mcg, 400mcg, 600mcg, 800mcg

CONTRAINDICATIONS

Opioid-nontolerant patients, management of acute or postoperative pain, including headache/migraine and dental pain.

WARNINGS/PRECAUTIONS

Increased risk of respiratory depression in patients with underlying respiratory disorders and in elderly/debilitated. May impair mental and/or physical abilities. Caution with chronic obstructive pulmonary disease or preexisting medical conditions predisposing to respiratory depression; may further decrease respiratory drive to the point of respiratory failure. May obscure clinical course of head injuries; use extreme caution in patients who may be susceptible to the intracranial effects of carbon dioxide retention (eg, with evidence of increased intracranial pressure or impaired consciousness). Application-site reactions (paresthesia, ulceration, bleeding) reported. Avoid use during labor and delivery. Caution with renal/hepatic impairment, bradyarrhythmias, and in elderly.

ADVERSE REACTIONS

Respiratory depression, headache, N/V, constipation, dizziness, dyspnea, somnolence, fatigue, anemia, asthenia, abdominal pain, dehydration, peripheral edema, diarrhea, anorexia.

DRUG INTERACTIONS

See Boxed Warning. CYP3A4 inducers (eg, carbamazepine, efavirenz, modafinil, phenobarbital, pioglitazone, rifampin, St. John's wort) may decrease levels. Respiratory depression is more likely to occur when given with other drugs that depress respiration. Increased depressant effects with other CNS depressants (eg, sedatives, hypnotics, tranquilizers, skeletal muscle relaxants, sedating antihistamines, alcohol); consider adjusting fentanyl dose if warranted. Not recommended for use in patients who have received MAOIs within 14 days.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Opioid analgesic; has not been established. Known to be μ-opioid receptor agonist; specific CNS opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and play a role in analgesic effects.

PHARMACOKINETICS

Absorption: Readily absorbed. Absolute bioavailability (65%). Administration of variable doses resulted in different pharmacokinetic parameters. **Distribution:** V_d=25.4L/kg; plasma protein binding (80-85%); found in breast milk; crosses placenta. **Metabolism:** Liver and intestinal mucosa via CYP3A4; norfentanyl (metabolite). **Elimination:** Urine (<7%, unchanged), feces (1%, unchanged). $T_{1/2}$=2.63 hrs (100mcg), 4.43 hrs (200mcg), 11.09 hrs (400mcg), 11.7 hrs (800mcg).

ASSESSMENT

Assess for degree of opioid tolerance, previous opioid dose, type and severity of pain, general condition and medical status, and any other conditions where treatment is contraindicated or cautioned. Assess for hypersensitivity to the drug, renal/hepatic impairment, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of respiratory depression, impairment of mental/physical abilities, application-site reactions, bradycardia, drug abuse/addiction, and other adverse reactions.

PATIENT COUNSELING

Instruct outpatients to enroll in the TIRF REMS Access program. Instruct to keep drug out of reach of children. Advise to take ud and to not share it with anyone else. Instruct to notify physician if breakthrough pain is not alleviated or worsens after taking the drug. Inform that drug may impair mental/physical abilities; caution against performing activities that require high level of attention (eg, operating machinery/driving). Advise not to combine

with alcohol, sleep aids, or tranquilizers except by order of prescribing physician. Instruct to notify physician if pregnant or planning to become pregnant. Inform of proper storage, administration, and disposal.

STORAGE

20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). Protect from freezing and moisture.

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