Lazanda (fentanyl) - Drug Summary

Depomed, Inc.

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Lazanda
(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 Lazanda. 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

Pain

Management of Breakthrough Pain in Cancer Patients Already Receiving and Tolerant to Opioid Therapy for Underlying Persistent Cancer Pain:
≥18 Years:
Initial (Including Switching from Another Fentanyl Product):
One 100mcg spray (1 spray in 1 nostril); if adequate analgesia is obtained w/in 30 min, treat subsequent episodes w/ this dose
Titrate:
If adequate analgesia is not achieved w/ the first 100mcg dose, escalate dose in a step-wise manner over consecutive episodes until adequate analgesia w/ tolerable side effects is achieved
100mcg/dose: 1 x 100mcg spray
200mcg/dose: 2 x 100mcg spray (1 in each nostril)
400mcg/dose: 4 x 100mcg spray (2 in each nostril) or 1 x 400mcg spray
800mcg/dose: 2 x 400mcg spray (1 in each nostril)
Confirm dose w/ a 2nd episode of breakthrough pain and review experience if dose is appropriate or further adjustment is warranted
Wait at least 2 hrs before treating another episode of breakthrough cancer pain
Maint:
Use the established dose for each subsequent episode; limit to ≤4 doses/day and wait at least 2 hrs before treating another episode
May use rescue medication if pain relief is inadequate after 30 min following dosing or if a separate episode occurs before the next dose is permitted
Max: 800mcg

DOSING CONSIDERATIONS

Renal Impairment
Severe: Use w/ caution; titrate to clinical effect

Hepatic Impairment
Severe: Use w/ caution; titrate to clinical effect

Discontinuation
No Longer Requires Opioid Therapy: Consider discontinuation along w/ a gradual downward titration of other opioids
Continuing to Take Chronic Opioid Therapy but No Longer Requires Treatment for Breakthrough Pain: Therapy can be discontinued immediately

Other Important Considerations
Dose Readjustment:
Response (Analgesia or Adverse Reactions) to Titrated Dose Markedly Changes: An adjustment may be necessary
>4 Episodes of Breakthrough Pain/Day: Reevaluate the dose of the long-acting opioid used; if the long-acting opioid or dose of long-acting opioid is changed, reevaluate and retitrate the Lazanda dose as necessary

ADMINISTRATION

Intranasal route

Prime device before use by spraying into the pouch (4 sprays total)
If not used for 5 days, reprime by spraying once
Insert nozzle of the bottle a short distance (about 1/2 inch or 1cm) into nose and point towards bridge of nose, tilting bottle slightly
Press down firmly on the finger grips until a click is heard and the number in the counting window advances by 1
Fine mist spray is not always felt; rely on audible click and dose counter to confirm a spray has been administered
Refer to PI for further priming and disposal instructions

HOW SUPPLIED

Spray: 100mcg/spray, 400mcg/spray

CONTRAINDICATIONS

Opioid non-tolerant patients; management of acute or postoperative pain, including headache/migraine, or dental pain; known intolerance or hypersensitivity to any of its components or the drug fentanyl.

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 COPD or preexisting medical conditions predisposing to respiratory depression; may further decrease respiratory drive to the point of respiratory failure. Extreme caution in patients who may be susceptible to intracranial effects of CO_2 retention (eg, with evidence of increased intracranial pressure or impaired consciousness). May obscure the clinical course of head injuries. May produce bradycardia; caution with bradyarrhythmias. Avoid use during labor and delivery. Caution in the elderly.

ADVERSE REACTIONS

Respiratory depression, N/V, somnolence, dizziness, headache, constipation, pyrexia.

DRUG INTERACTIONS

See Boxed Warning. Increase dose conservatively when beginning therapy with or increasing dose of CYP3A4 inhibitors. Not recommended with MAOIs or within 14 days of discontinuation of MAOIs. Increased depressant effects with other CNS depressants (eg, other opioids, sedatives/hypnotics, skeletal muscle relaxants); may require adjustment of Lazanda dose. CYP3A4 inducers (eg, barbiturates, carbamazepine, efavirenz) may decrease levels; adjust dose of Lazanda accordingly. Vasoconstrictive nasal decongestants such as oxymetazoline may decrease efficacy; avoid titration while patient is experiencing an acute episode of rhinitis as it could lead to incorrect dose identification. Respiratory depression reported with other drugs that depress respiration.

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: Administration of various doses resulted in different parameters. **Distribution:** V_d=4L/kg; plasma protein binding (80-85%); crosses placenta; found in breast milk. **Metabolism:** Liver and intestinal mucosa via CYP3A4; norfentanyl (metabolite). **Elimination:** Urine (<7%, unchanged), feces (1%, unchanged); $T_{1/2}$=21.9 hrs (100mcg), 24.9 hrs (200mcg and 800mcg), 15 hrs (400mcg).

ASSESSMENT

Assess for degree of opioid tolerance, previous opioid dose, level of pain intensity, type of pain, patient's 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, drug abuse/addiction, bradycardia, hypersensitivity reactions, and other adverse reactions.

PATIENT COUNSELING

Inform outpatients to enroll in the TIRF REMS Access program. Explain that therapy may be fatal in children, in individuals for whom it was not prescribed, and in those who are not opioid tolerant. Counsel on proper administration and disposal. Advise to take drug as prescribed and to avoid sharing it with anyone else. Instruct not to take medication for acute or postoperative pain, pain from injuries, headache, migraine, or any other short-term pain. 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, driving/using heavy machinery). Advise not to combine with alcohol, sleep aids, or tranquilizers, except if ordered by the physician. Instruct to notify physician if pregnant or planning to become pregnant.

STORAGE

Up to 25°C (77°F). Do not freeze. Protect from light.

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