Lucemyra (lofexidine HCl)

NEW PRODUCT SLIDESHOW
- **Brand name:** Lucemyra
- **Generic name:** Lofexidine HCl
- **Pharmacological class:** Central alpha-2 agonist
- **Strength and Formulation:** 0.18mg; tabs
- **Manufacturer:** US WorldMeds, LLC
- **How supplied:** Tabs—36, 96
- **Legal Classification:** Rx
Lucemyra
Indication

- Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults
Initially 3 tabs 4 times daily (5–6hrs between doses) during peak withdrawal symptoms for up to 14 days

- Max single dose: 0.72mg (4 tabs)
- Max daily dose: 2.88mg (16 tabs)

Discontinue gradually over 2–4 days (eg, reduce by 1 tab/dose every 1–2 days)
Dosage & Administration

- **Hepatic impairment** (moderate): 2 tabs 4 times daily; (severe): 1 tab 4 times daily

- **Renal impairment** (mild or moderate): 2 tabs 4 times daily; (severe, ESRD, or on dialysis): 1 tab 4 times daily
Considerations for Special Populations

- **Pregnancy**: Not established
- **Nursing mothers**: Caution should be exercised; consider mother’s need and potential adverse effects on infant
- **Pediatric**: Not established
- **Elderly (>65yrs)**: Consider dose adjustment
- **Hepatic or renal impairment**: See Dosing
Warnings/Precautions

- Risk of hypotension, bradycardia, syncope
- **Monitor vital signs** before dosing and for symptoms of bradycardia and orthostasis
- **Avoid** in severe coronary insufficiency, recent MI, cerebrovascular disease, chronic renal failure, marked bradycardia, concomitant pulse or BP-lowering medications, congenital long QT syndrome
Warnings/Precautions

- Correct electrolyte abnormalities prior to initiation
- CHF, bradyarrhythmias, hepatic/renal impairment, concomitant QT-prolonging drugs (e.g., methadone): monitor ECG
- Increased risk of opioid overdose after opioid discontinuation
Warnings/Precautions

- Use only in conjunction with comprehensive management program for treatment of opioid use disorder
- Avoid abrupt cessation
- Known CYP2D6 poor metabolizers: monitor
Interactions

- Increased QT prolongation with concomitant methadone; monitor ECG
- May antagonize oral naltrexone when concomitant within 2hrs of Lucemyra
- Potentiates CNS depressant effects of benzodiazepines
Interactions

- May potentiate alcohol, barbiturates, other sedatives
- Potentiated by CYP2D6 inhibitors (e.g., paroxetine); monitor for orthostatic hypotension, bradycardia
Adverse Reactions

- Orthostatic hypotension
- Bradycardia
- Hypotension
- Dizziness
- Somnolence
- Sedation
- Dry mouth
- Discontinuation symptoms (e.g., diarrhea, insomnia, anxiety, chills, others)
Mechanism of Action

- Lofexidine is a central alpha-2 adrenergic agonist that binds to receptors on adrenergic neurons.
- This reduces the release of norepinephrine and decreases sympathetic tone.
Clinical Studies

- **Study 1** (N=602) was a 2-part, efficacy, safety, and dose-response study in patients meeting DSM-IV criteria for opioid dependence who were physically dependent on short-acting opioids (eg, heroin, hydrocodone, oxycodone)
Clinical Studies

- The first part consisted of 7 days of inpatient treatment with Lucemyra 2.16mg daily, 2.88mg daily, or matching placebo.
- Patients who completed Days 1–7 were eligible for the second part of the study to receive variable doses of Lucemyra (max 2.88mg daily) for up to an additional 7 days (Days 8–14) in either an inpatient or outpatient setting.
Clinical Studies

- The two endpoints were the mean SOWS-Gossop total score on Days 1–7, and the proportion of patients that completed 7 days of treatment.
- SOWS-Gossop total scores range from 0-30 where a higher score indicates a greater withdrawal symptom severity.
- The mean SOWS-Gossop scores for Days 1–7 were 8.8, 6.5, and 6.1 for placebo, Lucemyra 2.16mg, and Lucemyra 2.88mg, respectively.
Clinical Studies

- Mean differences between Lucemyra 2.16mg with placebo (−2.3, 95% CI: −3.4, −1.2) and Lucemyra 2.88mg with placebo (−2.7, 95% CI: -3.9, -1.6) were both statistically significant
- Of the study patients, 28% of placebo, 41% of Lucemyra 2.16mg, and 40% of Lucemyra 2.88mg patients completed 7 days of treatment
**Clinical Studies**

- **Study 2** (N=264) was an inpatient, randomized, multicenter, double-blind, placebo-controlled study where patients were given Lucemyra 2.88mg daily or matching placebo for 5 days.
  - All patients then received placebo on Days 6–7 and were discharged on Day 8.
Clinical Studies

- The mean SOWS-Gossop scores for Days 1–5 were 8.9 and 7.0 for placebo and Lucemyra 2.88mg, respectively (mean difference −1.9, 95% CI: −3.2, −0.6)
  - The difference was statistically significant
Clinical Studies

- Of the study patients, 33% of placebo and 49% of Lucemyra patients completed 5 days of treatment

- For more clinical trial data, see full labeling
New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/lucemyra/drug/34851/