Lucemyra (lofexidine HCl)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **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


Rx only
NDC 27505-050-96
Lucemyra™
(lofexidine) tablets
0.18 mg
Store and dispense
in original container.
Protect from heat and moisture.
Do not remove desiccants.
Keep the bottle tightly closed.
Keep out of reach of children.
96 tablets
US WorldMeds
LFX

Indication

- Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults

Dosage & Administration

- 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 (eg, 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 (eg, paroxetine); monitor for orthostatic hypotension, bradycardia

Adverse Reactions

- Orthostatic hypotension
- Bradycardia
- Hypotension
- Dizziness
- Somnolence
- Sedation
- Dry mouth
- Discontinuation symptoms (eg, 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/