# I TOLD MY DOCTOR I WANTED TO STOP TAKING MY OPIOID PAIN MEDICINE.

## WE CAME UP WITH A PLAN.

All photos in this guide are actor portrayals.

**Stopping opioid use suddenly can result in severe, sometimes flu-like, withdrawal symptoms.[1,2]**

**LUCEMYRA® is the only FDA-approved, non-opioid, non-addictive treatment for relief of multiple symptoms of opioid withdrawal that may happen when you stop taking an opioid suddenly.[3]**

Lucemyra®
(lofexidine) tablets 0.18 mg

***Relieve the symptoms, retake control***

**What is LUCEMYRA?**

LUCEMYRA is a non-opioid prescription medicine used in adults to help with the symptoms of opioid withdrawal that may happen when you stop taking an opioid suddenly.

LUCEMYRA will not completely prevent the symptoms of opioid withdrawal and is not a treatment for opioid use disorder.

**Please see the full Important Safety Information on back cover and distributed full Prescribing Information and Patient Information.**

# *Understanding Opioid Withdrawal Syndrome (OWS) and how it might impact you*

## OWS occurs when someone suddenly stops taking opioids, or rapidly reduces their opioid dosage, and experiences severe, sometimes flu-like, symptoms[1,2]

Withdrawal symptoms are most severe in the first 2 to 3 days after stopping the opioid. Symptoms may continue for 1 to 3 weeks, depending on the type of opioid.[4,5]

## OWS is not your fault

OWS is a physical response that can happen when someone develops a physical need for opioids after using them to relieve pain. This physical dependence often occurs even when taking opioids as prescribed by your healthcare provider.[1,6-8]

## Regardless of when you started taking opioids, it's important to talk to your healthcare provider about your ongoing treatment goals

Part of your treatment plan should include how long you can expect to stay on opioids and how you can help relieve the symptoms that may occur when you stop taking them. This is important because you can begin to feel a physical need for your opioid pain medicine as soon as 5 days after starting to use it.[6]

**Important Safety Information**

LUCEMYRA can cause serious side effects, including low blood pressure, slow heart rate, and fainting. Watch for symptoms of low blood pressure or heart rate, including dizziness, lightheadedness, or feeling faint at rest or when quickly standing up; if you experience these symptoms, call your healthcare provider right away and do not take your next dose of LUCEMYRA until you have talked to your healthcare provider. Avoid becoming dehydrated or overheated and be careful not to stand up too suddenly from lying or sitting, as these may increase your risk of low blood pressure and fainting.

# *How does physical dependence to opioids develop?*

## It starts with tolerance

Tolerance develops when the body's response to opioids changes. A person who develops tolerance to opioids will need higher dosages to feel the same pain relief.[7]

## Tolerance leads to physical dependence

A person can develop physical dependence to opioids as soon as 5 days after starting to use them.[6] So, like OWS, physical dependence is not your fault. Your healthcare provider knows this and wants to help you get through withdrawal.

People who are physically dependent on opioids will experience physical symptoms of withdrawal when they stop using opioids.[7] Stopping opioids resolves physical dependence after a person gets through withdrawal.

## People who are physically dependent on opioids may be at risk of developing Opioid Use Disorder (OUD)[2]

Opioid Use Disorder (OUD) is a combination of symptoms and behaviors related to substance use that can occur in people with or without a legitimate need for pain relief.

This includes[9]:

- People with a long-term, uncontrollable urge/craving to continue taking opioids despite not having a legitimate medical need
- People with a medical condition that requires opioid pain relief, who then take far more opioid medication than is needed for pain relief

Addiction is now part of Opioid Use Disorder (OUD).[7]

**Please see the full Important Safety Information on back cover and the distributed full Prescribing Information and Patient Information.**

## *Most common opioid withdrawal symptoms include[10]:*

- Aches and pains
- Stomach cramps
- Feeling sick (nausea, vomiting, diarrhea)
- Muscle spasms/twitching
- Insomnia/problems sleeping
- Feelings of coldness/chills
- Muscular tension
- Heart pounding
- Runny eyes
- Yawning

### Recognizing the symptoms of opioid withdrawal

Withdrawal symptoms include both mental distress and physical discomfort.[3] Sometimes it's hard to tell the difference between withdrawal symptoms of physical discomfort and the original pain your healthcare provider prescribed the opioid to treat.[11]

**Important Safety Information (continued)**

When your treatment is complete, you will need to stop taking LUCEMYRA gradually, or your blood pressure could increase.

After a period of not using opioid drugs, you can become more sensitive to the effects of opioids if you start using them again. This may increase your risk of overdose and death.

# *LUCEMYRA® can help you get through withdrawal*

## What is LUCEMYRA?

LUCEMYRA is the only FDA-approved, non-opioid, non-addictive prescription medicine for relief of multiple symptoms of opioid withdrawal that may happen when you stop taking an opioid suddenly.[1]

## Provided the biggest improvement in symptom relief on Day 2 and Day 3 of opioid withdrawal—when symptoms were often most severe[1,12]

LUCEMYRA has been studied in people with physical opioid dependence who stopped taking opioids suddenly and were in active withdrawal.[9,12,13] These studies showed that LUCEMYRA helped relieve symptoms on the first day of treatment and greatly improved symptom relief by Day 3.[1,12]

### What to expect from LUCEMYRA treatment[1,12]

**DAY 1**

Patients **started to feel** some symptom relief

**DAY 2**

Patients **experienced an improvement** in symptom relief

**DAY 3**

Patients **continued to feel improvement** in symptom relief, as withdrawal symptoms continued to decrease

**LUCEMYRA continued to be effective through Day 7 of treatment.[1,12]**

**LUCEMYRA is not a treatment for Opioid Use Disorder (OUD), which is also called opioid addiction.** If you have been diagnosed with OUD, your healthcare provider may prescribe LUCEMYRA as part of a complete treatment program for your OUD. This program continues after LUCEMYRA treatment is completed and may also include maintenance medications combined with behavioral counseling.

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## *LUCEMYRA® helps correct a chemical imbalance that causes withdrawal symptoms[1,3]*

**Your healthcare provider can tell you about how opioids can affect the chemical balance in your brain and how LUCEMYRA can help.**

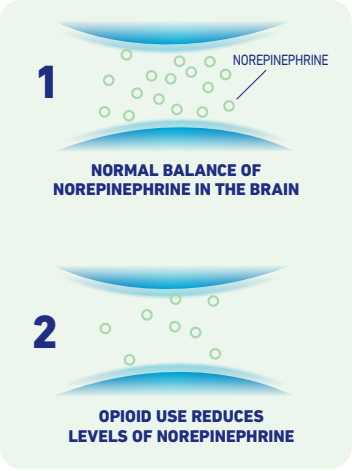
**Important Safety Information (continued)**

Before taking LUCEMYRA, tell your healthcare provider about all your medical conditions, including if you have low blood pressure, slow heart rate, any heart problems including history of heart attack or a condition called long QT syndrome, liver or kidney problems, or if you drink alcohol. Tell your healthcare provider if you are pregnant, plan on becoming pregnant, or are breastfeeding; it is not known if LUCEMYRA can harm your unborn baby or whether LUCEMYRA passes into your breast milk.

# *How does LUCEMYRA work?*

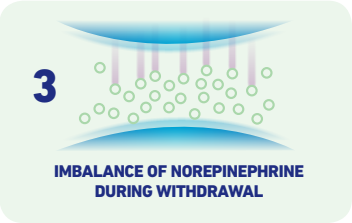
## Long-term opioid use changes the way nerve cells work in the brain[2]

- When opioids are initially taken, the brain produces lower levels of a naturally occurring hormone, called norepinephrine, that can affect breathing, muscle tension, and ability to sleep
- Over time, your nerve cells become used to having opioids around. Because opioids reduce the levels of norepinephrine, your body responds by adjusting these levels



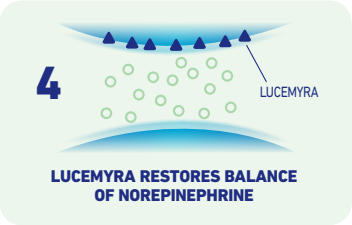

## When opioids are taken away suddenly, there is an imbalance of norepinephrine[2]

- The person will begin to feel lots of very unpleasant feelings and reactions; these are known as withdrawal symptoms




## LUCEMYRA helps adjust the balance of norepinephrine in the areas of your brain that cause withdrawal symptoms[1]

- This helps restore the chemical balance and helps relieve the symptoms that occur during opioid withdrawal

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# Possible Side Effects

## Most commonly experienced side effects with LUCEMYRA®[1]:

- Low blood pressure or symptoms of low blood pressure, such as lightheadedness
- Slow heart rate
- Dizziness
- Sleepiness
- Dry mouth

These are not all the possible side effects of LUCEMYRA.[1]

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to US WorldMeds at 1-833-LUCEMYRA.

## You may still experience symptoms of withdrawal[1]

- LUCEMYRA may mitigate, but not completely prevent, the symptoms associated with opioid withdrawal syndrome, which may include feeling sick (nausea, vomiting, diarrhea), stomach cramps, muscle spasms (twitching), feelings of coldness (chills), heart pounding, muscular tension, aches and pains, yawning, runny eyes, and sleep problems (insomnia)[1]

**References: 1.** Kosten TR, George TP. The neurobiology of opioid dependence: implications for treatment. *Sci Pract Perspect.* 2002;13-20. **2.** Shigakova F. Clinical manifestations of the opiate withdrawal syndrome. *Int J Biomed.* 2015;5(3):151-154. **3.** LUCEMYRA® (lofexidine) [Prescribing Information]. USWM, LLC; 2018. **4.** Kosten, TR, O'Connor PG. Management of drug and alcohol withdrawal. *N Engl J Med.* 2003;348:1786-1795. **5.** Kleber H. Opioids: detoxification. In: Galanter M, Kleber HD (eds). *Textbook of Substance Abuse Treatment.* 2nd ed. Washington, DC: American Psychiatric Press; 1999:251-269. **6.** Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015. *MMWR Morb Mortal Wkly Rep.* 2017;66(10):265-269. **7.** Volkow ND, McClellen AT. Opioid abuse in chronic pain—misconceptions and mitigation strategies. *N Engl J Med.* 2016;374:1253-1263. **8.** Centers for Disease Control and Prevention. Module 3: communicating with patients. Transcript. 2016. https://www.cdc.gov/drugoverdose/training/communicating/accessible/training.html. Accessed June 20, 2018. **9.** American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5™). Arlington, VA, American Psychiatric Association, 2013. **10.** Vernon MK, Reinders S, Mannix S, et al. Psychometric evaluation of the 10-item Short Opiate Withdrawal Scale-Gossop (SOWS-Gossop) in patients undergoing opioid detoxification. *Addict Behav.* 2016;60:109-116. **11.** Rosenblum A, Marsch LA, Joseph H, Portenoy RK. Opioids and the treatment of chronic pain: controversies, current status, and future directions. *Exp Clin Psychopharmacol.* 2008;16(5):405-416. **12.** Data on file. US WorldMeds; 2017. **13.** Gorodetzky CW, Walsh SL, Martin PR, Saxon AJ, Gullo KL. A phase III, randomized, multi-center, double blind, placebo controlled study of safety and efficacy of lofexidine for relief of symptoms in individuals undergoing inpatient opioid withdrawal. *Drug Alcohol Depend.* 2017;176:79-88.

### Important Safety Information (continued)

Especially tell your healthcare provider if you take benzodiazepines, barbiturates, tranquilizers, or sleeping pills, as taking these with LUCEMYRA can cause serious side effects.

# *Taking LUCEMYRA*

**How a Healthcare Provider May Prescribe LUCEMYRA[1]**

**3** TABLETS **4** TIMES **7** DAYS

- LUCEMYRA dosing is usually three tablets taken orally, four times a day, for 5-7 days, followed by a gradual reduction in dosing over 2-4 days
  - **Make sure you follow the exact dosing instructions provided by your healthcare provider**
- Be sure to **wait 5 to 6 hours** between each dose
- LUCEMYRA can be taken **with or without food**
- LUCEMYRA can be **taken for up to 14 days** if you and your healthcare provider decide that you need continued symptom relief
- **Do not** stop taking LUCEMYRA without first talking to your healthcare provider

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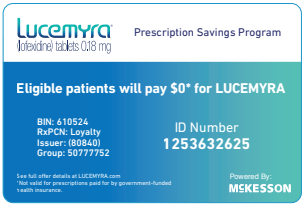
# *The LUminate™ Support Program*

US WorldMeds is committed to helping you with your plan to stop using opioids and get through opioid withdrawal. That's why we've created the LUminate Support Program—to offer you savings, tools, and resources designed to support you as you begin your treatment with LUCEMYRA®.

## Eligible patients will pay $0* for LUCEMYRA




- Simply take your LUCEMYRA prescription to a participating pharmacy and the savings can be automatically applied to your co-pay
- For more information about the LUCEMYRA Prescription Savings Program, visit LUCEMYRA.com
- Eligible patients without health insurance can apply for the US WorldMeds Patient Assistance Program (UPAP), which provides LUCEMYRA at no cost to those patients who meet certain income requirements

## Get added support designed to assist you while taking LUCEMYRA and going through opioid withdrawal

- **Getting support and encouragement can be critical** while you are going through opioid withdrawal
- **The LUminate Support Program offers you tools and resources** to support you during each day of treatment with LUCEMYRA, including the LUminate Support App
- The LUminate Support App helps **guide you as you go through opioid withdrawal** with:
  - Dose Tracking/Reminders
  - Supportive messages each day of treatment
  - Symptom Library (including advice and tips for relief)
  - Meditation Timer

**No need to sign up—simply download the app to start immediately!**

* Patients whose prescriptions will be paid for in part or in whole by Medicare, Medicaid, or any similar federal or state healthcare program, are not eligible for savings or rebates according to federal and state law. Patients must visit a participating pharmacy for savings or rebates on their LUCEMYRA prescriptions. Maximum benefits may apply. Other restrictions may apply. For more information, please see Terms and Conditions at LUCEMYRA.com.

**Important Safety Information (continued)**

The most common side effects of LUCEMYRA include low blood pressure or symptoms of low blood pressure such as lightheadedness, slow heart rate, dizziness, sleepiness, and dry mouth.

LUminate® Support Program

## SUPPORT APP

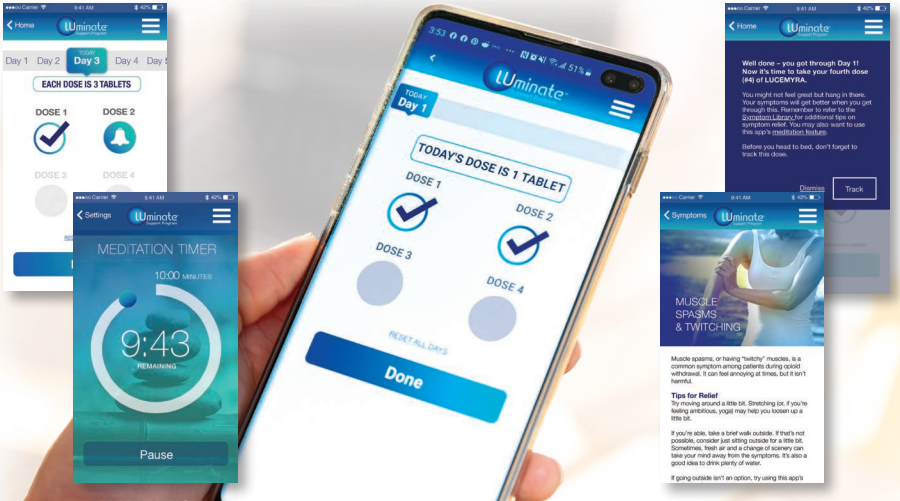
**AVAILABLE AT:**

Download on the App Store

GET IT ON Google Play

**DOSE TRACKING/ REMINDERS**

**SUPPORTIVE MESSAGES EACH DAY OF TREATMENT**




**MEDITATION TIMER**

**SYMPTOM LIBRARY**
(INCLUDING ADVICE AND TIPS FOR RELIEF)

Learn more about the LUminate Support Program at **LUCEMYRA.com**

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**To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-833-LUCEMYRA. You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

US WorldMeds®

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