

- **Lucemyra®**
  - Tablets: 0.18 mg

*If you or someone you know is in crisis, please call 911 and/or the toll-free National Suicide Prevention Lifeline at 800-273-TALK (8255) to speak with a trained crisis counselor 24/7. A help line and other resources are also available through the National Alliance on Mental Illness at [nami.org](https://www.nami.org).*



## What is lofexidine and what does it treat?

Lofexidine is a non-opioid prescription medication used in adults to help with the symptoms of opioid withdrawal that may happen when you stop taking an opioid suddenly. Lofexidine will not completely prevent the symptoms of opioid withdrawal.

Symptoms of opioid withdrawal include:

- Aches and pains
- Stomach cramps
- Feeling sick
- Muscle spasms/twitching
- Insomnia/problems sleeping
- Feeling of coldness/chills
- Muscular tension
- Heart pounding
- Runny eyes
- Yawning

## What is the most important information I should know about lofexidine?

Lofexidine is not a treatment for opioid use disorder. If you have been diagnosed with opioid use disorder, your health care provider may prescribe lofexidine as part of a complete treatment program for your opioid use disorder.

Lofexidine may cause low blood pressure, slow heart rate, dizziness, and fainting. Notify your health care provider right away if you experience these symptoms. If you take lofexidine and have any of these symptoms, do not take your next dose until you have talked to your health care provider. You should stay well-hydrated and avoid becoming overheated during treatment with lofexidine because that can increase your risk of low blood pressure and fainting. You should also be careful to stand up slowly from lying down or sitting.

After the period of time of not using opioid medications, you will respond to lower doses of opioids for pain. Do not begin using opioids at the doses you tolerated prior to starting lofexidine. This may increase your risk of overdose and death.

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.

Lofexidine can potentiate the central nervous system depressant effects of benzodiazepines, alcohol, barbiturates, and other sedating drugs.

Lofexidine should be used in conjunction with a comprehensive treatment program.

Lofexidine treatment should be discontinued by slowly decreasing the dose usually over 2 to 4 days to minimize withdrawal symptoms.

Patients with opioid use disorders are at high risk for depression and suicidal thoughts. If you experience any increased thoughts of suicide, call 911 or go to your closest emergency room.

### Are there specific concerns about lofexidine and pregnancy?

There is limited data on lofexidine use in pregnant women to inform about drug-associated risk. The safety of lofexidine in pregnant women has not been established. In animal studies, there was evidence of offspring having reduced body weights and developmental delays, but these results cannot be applied to humans.

There is no information regarding the presence of lofexidine or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Caution should be exercised when lofexidine is administered to a nursing woman.

Your health care provider and you should consider your clinical need for lofexidine and any other potential adverse effects on breastfed children from lofexidine or from the underlying maternal condition.

### What should I discuss with my health care provider before taking lofexidine?

- If you have low blood pressure
- If you have a slow heart rate
- If you have any heart problems, including history of heart attack or a condition called long QT syndrome
- If you have liver or kidney problems
- If you drink alcohol
- If you are pregnant or plan to become pregnant. It is not known if lofexidine can harm your unborn baby.
- If you are breastfeeding or plan to breastfeed. It is not known if lofexidine passes into your breast milk. Talk to your health care provider about the best way to feed your baby during treatment with lofexidine.
- Tell your health care provider about all of the medications you take, including prescription and over-the-counter medications, vitamins, herbal supplements, and any medications you may take for the individual symptoms of opioid withdrawal (such as pain relievers or medications for upset stomach).
- Tell your health care provider if you take benzodiazepines, barbiturates, tranquilizers, or sleeping pills. Taking lofexidine with these medications can cause serious side effects. Ask your health care provider or pharmacist if you are not sure if you are taking any of these medications.

### How should I take lofexidine?

Lofexidine should be taken exactly as your health care provider tells you to take it. Do not change your dose or stop taking lofexidine without talking to your health care provider.

Lofexidine is usually dosed at 0.54 mg 4 times daily, with at least 5 to 6 hours between each dose. The dosing of lofexidine is adjusted based on your withdrawal symptoms and how well you are tolerating the drug. Lofexidine can be continued for up to 14 days if needed. Take lofexidine with or without food.

You should drink plenty of non-caffeine liquids, unless told otherwise by your doctor.

You should never take more than 16 tablets in 1 day and no single dose should exceed 4 tablets.

Consider using a calendar, pillbox, alarm clock, or cell phone alert to help you remember to take your medication. You may also ask a family member or friend to remind you or check in with you to be sure you are taking your medication.

## What happens if I miss a dose of lofexidine?

If you miss a dose of lofexidine, take it as soon as you remember unless it is closer to the time of your next dose. Do not double your next dose or take more than what is prescribed. You should wait at least 5 to 6 hours between each dose.

## What should I avoid while taking lofexidine?

Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how lofexidine affects you.

Avoid drinking alcohol, using opioid pain medications (such as codeine, hydrocodone, oxycodone, or morphine), or using illegal drugs while you are taking lofexidine. They may increase adverse effects (e.g., sedation) of the medication.

Keep in mind that some cough syrups may contain opioid pain medication. Discuss all medications with your doctor and pharmacist prior to taking lofexidine.

## What happens if I overdose with lofexidine?

If an overdose occurs, call your doctor or 911. You may need urgent medical care. You may also contact the poison control center at 1-800-222-1222.

Signs and symptoms of an overdose include:

- Low blood pressure
- Slow heart rate
- Sedation

## What are the possible side effects of lofexidine?

### Common side effects

- Low blood pressure or symptoms of low blood pressure (e.g., lightheadedness)
- Slow heart rate
- Dizziness
- Sleepiness
- Dry mouth

### Rare/serious side effects

- Irregular heart rhythms: Notify your health care provider if you have a history of congestive heart failure, slow heart rate, liver or kidney problems.
- Opioid overdose: If you complete opioid discontinuation, you are likely to have a reduced tolerance to opioids and are at an increased risk of a fatal overdose if resume opioid use.
- Discontinuation syndrome: Marked rise in blood pressure and symptoms of diarrhea, insomnia, anxiety, chills, sweating and extremity pain. Lofexidine must be discontinued gradually.

## Are there any risks for taking lofexidine for long periods of time?

Lofexidine is not indicated for long-term use. Lofexidine treatment usually last for 5 to 7 days following last opioid use. It may only be continued up to 14 days with dosing guided by symptoms. Lofexidine must be discontinued gradually over a 2 to 4-day period.

## What other medications may interact with lofexidine?

Lofexidine may increase the depressant effects of alcohol, benzodiazepines, barbiturates and other sedating drugs.

Paroxetine (Paxil®) may increase the absorption of lofexidine, which can increase the side effects of lofexidine (e.g., low blood pressure, slow heart rate).

Lofexidine may reduce the effectiveness of oral naltrexone (Revia®) when given within 2 hours of each other.

Taking lofexidine and methadone together may cause irregular heart rhythms. Concurrent use requires cardiac monitoring.

Your pharmacist or doctor will help you to determine if other medications you take can interfere with the effects of lofexidine.

## How long does it take for lofexidine to work?

Lofexidine will begin working shortly after taking one dose.

## Summary of Black Box Warnings

Lofexidine does not have any Black Box Warnings.