Zurnai™ (nalmefene injection)
1.5 mg/0.5 mL Auto-Injector

Opioid overdoses are full of unknowns.
Be ready when it matters most.

EQUIP YOUR TEAM WITH THE FIRST AND ONLY NALMEFENE AUTO-INJECTOR[1]

Actor portrayals.

INDICATIONS AND USAGE

ZURNAI is indicated for the emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression.

ZURNAI is intended for immediate administration as emergency therapy in settings where opioids may be present.

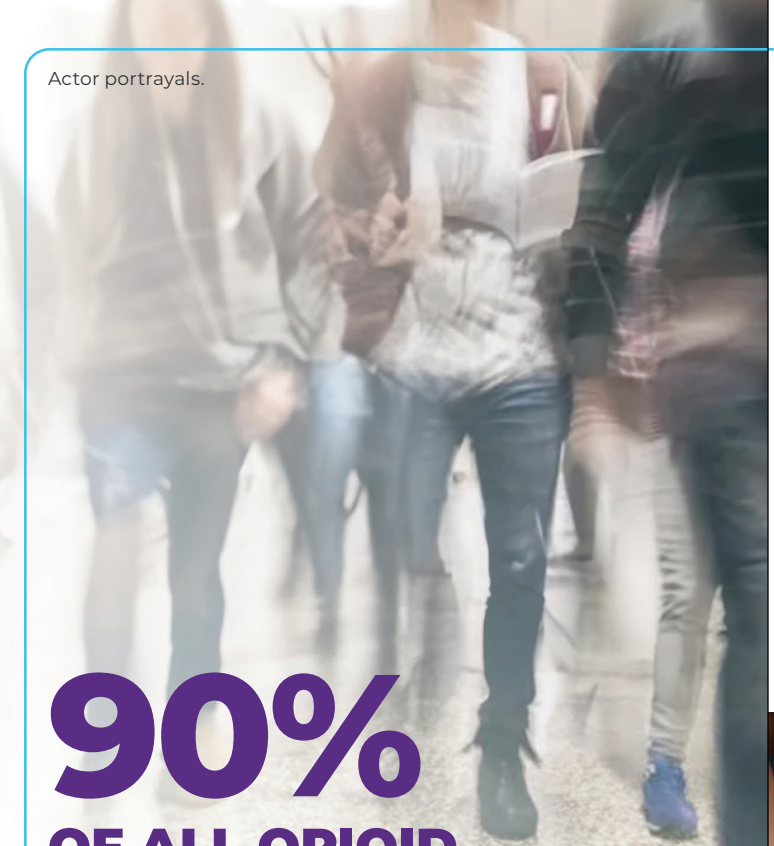
ZURNAI is not a substitute for emergency medical care.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ZURNAI is contraindicated in patients known to be hypersensitive to nalmefene hydrochloride or to any other ingredients in the product.

Please see additional IMPORTANT SAFETY INFORMATION throughout and Full Prescribing Information.



Actor portrayals.

90%

OF ALL OPIOID OVERDOSE DEATHS IN 2023 INVOLVED SYNTHETIC OPIOIDS[2]

Accidental opioid exposure is a substantial risk.[3,4]

DID YOU KNOW?

5 out of every 10 fentanyl-laced pills seized by the US Drug Enforcement Administration contain a lethal dose.[5]

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Risk of Recurrent Respiratory and Central Nervous System Depression

A recurrence of respiratory depression is possible, therefore, keep the patient under continued surveillance and administer repeat doses of ZURNAI if necessary, using a new auto-injector with each dose while awaiting emergency medical assistance.

OPIOID OVERDOSE RISKS CONTINUE POST-DISCHARGE

The rate of fatal opioid overdoses, while alarming, is only part of the picture. By some estimates, for every fatal overdose, there are as many as **10 non-fatal overdoses treated in an emergency department**.[6] These patients face significant challenges after discharge.[7]

The National Institutes of Health supports development of stronger, longer-acting formulations of opioid antagonists to counteract high-potency synthetic opioids.[8]

Actor portrayals.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

Risk of Limited Efficacy with Partial Agonists or Mixed Agonist/Antagonists

Reversal of respiratory depression by partial agonists or mixed agonists/antagonists such as buprenorphine and pentazocine, may be incomplete. Repeat doses of ZURNAI may be required.

Please see additional IMPORTANT SAFETY INFORMATION throughout and Full Prescribing Information.

DURATION OF ACTION AS LONG AS MOST OPIOIDS[1]

While the duration of action of nalmefene is as long as most opioids, a recurrence of respiratory depression is possible, even after an apparently adequate initial response to ZURNAI treatment.

Not actual size.

Therefore, it is necessary to seek emergency medical assistance immediately after administration of the first dose of ZURNAI and to keep the patient under continued surveillance. A second dose may be necessary if there is recurrence of symptoms of opioid overdose.

Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

THE FIRST AND ONLY NALMEFENE AUTO-INJECTOR[1]

ZURNAI works fast[1]

In a pharmacodynamic study conducted in an experimental setting, time to onset of reversal of respiratory depression was observed between 2.5 to 5 minutes. Full recovery of respiratory drive was noted between 5 and 15 minutes after ZURNAI administration.

ZURNAI is long-acting[1]

In a pharmacokinetic study of 24 healthy adult volunteers, mean terminal elimination half-life was 9.07 hours.

The clinical implications of these findings for real-world overdose situations are unknown.

Clinically demonstrated safety profile[1]

The most common adverse reactions (incidence > 5%) are feeling hot, nausea, headache, dizziness, chills, vomiting, allodynia, palpitations, tinnitus, ear discomfort, feeling abnormal, burning sensation, hot flush, and irritability.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

Precipitation of Severe Opioid Withdrawal

The use of ZURNAI in patients who are opioid dependent may precipitate opioid withdrawal.

Abrupt postoperative reversal of opioid depression may result in adverse cardiovascular (CV) effects. These events have primarily occurred in patients who had preexisting CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of ZURNAI.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

Precipitation of Severe Opioid Withdrawal (cont)

In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may include the following signs and symptoms: convulsions, excessive crying, and hyperactive reflexes. Monitor the patient for the development of the signs and symptoms of opioid withdrawal.

Please see additional IMPORTANT SAFETY INFORMATION throughout and Full Prescribing Information.

GET TO KNOW THE ZURNAI AUTO-INJECTOR

Administration instructions

Step-by-step instructions for administering ZURNAI are included on the body of the auto-injector.

Safety seal

This device includes a safety seal that will break when the cap is removed.

Do not use the device if the safety seal is already broken or missing before use.

Not actual size.

Expiration date

Check the expiration date. Replace ZURNAI before the expiration date.

- ZURNAI is not a substitute for emergency medical care[1]

- 99.999% reliability, meeting US Food and Drug Administration requirements for emergency-use injectors[9]*
- 22-gauge needle can penetrate up to three layers of denim[9]

*Reliability of ZURNAI Auto-Injector was assessed in accordance with FDA guidance for emergency-use injectors; Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA, or ANDA: Guidance for Industry and Food and Drug Administration Staff.

ANDA=Abbreviated New Drug Application; BLA=Biologics License Application; NDA=New Drug Application.

Blue cap

Once the safety seal is broken and blue cap is removed, ZURNAI must be used immediately or disposed of properly.

Do not use if safety cap is missing or seal is broken.

Not actual size.

Viewing window

Liquid should be clear, colorless to light yellow and free of particles. You may see air bubbles. This is normal.

Window turns orange when injection is complete.

Needle guard

Reduces chance of accidental needle stick.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS (cont)

Risk of Opioid Overdose from Attempts to Overcome the Blockade

Attempts to overcome opioid withdrawal symptoms caused by opioid antagonists with high or repeated doses of exogenous opioids may lead to opioid intoxication and death.

IMPORTANT SAFETY INFORMATION (cont)

ADVERSE REACTIONS

Most common adverse reactions (> 5%) are feeling hot, nausea, headache, dizziness, chills, vomiting, allodynia, palpitations, tinnitus, ear discomfort, feeling abnormal, burning sensation, hot flush, and irritability.

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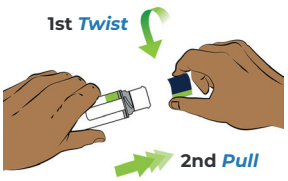
HOW TO USE ZURNAI[10]

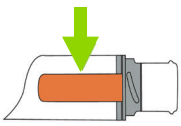
Refer to **Instructions for Use** for additional administration details.

1. **Twist** blue cap and then **pull**



2. **Push needle end** into **outer thigh** until **click**—then **hold for three seconds**

3. **Injection complete** when window is orange



4. **Call 911** and watch the person

Stay until the ambulance arrives

! If the person does not wake up within 2–5 minutes after injection, repeat steps 1–3 with a new ZURNAI Auto-Injector.[1]

IMPORTANT SAFETY INFORMATION (cont)

USE IN SPECIFIC POPULATIONS

Pregnancy

An opioid overdose is a medical emergency and can be fatal for the pregnant woman and fetus if left untreated. Treatment with ZURNAI for opioid overdose should not be withheld because of potential concerns regarding the effects of ZURNAI in the fetus.

Pediatric Use

The safety and effectiveness of ZURNAI for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, have not been established in pediatric patients younger than 12 years of age.

STORAGE AND HANDLING[1,10]

Store ZURNAI at controlled room temperature (68°F to 77°F)

- Do not freeze or refrigerate
- Store in a clean, dry place. Protect from light
- During storage, check ZURNAI through the viewing window of the auto-injector every 30 days. The liquid should be clear, colorless to light yellow. If the ZURNAI liquid is discolored, cloudy, or contains solid particles, replace it with a new ZURNAI
- Periodically check the expiration date and replace expired product as needed
- Cannot be reused

IMPORTANT SAFETY INFORMATION (cont)

USE IN SPECIFIC POPULATIONS (cont)

Geriatric Use

Clinical studies of nalmefene hydrochloride injection did not include sufficient number of subjects aged 65 and over to determine whether they respond differently from younger subjects.

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To report SUSPECTED ADVERSE REACTIONS, contact Knoa Pharma LLC at 1 888-726-7535, option 2, or FDA at 1-800-FDA-1088 or www.fda.gov/safety/medwatch.

Intended for healthcare professionals of the United States of America only.

Please see Full Prescribing Information.

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MAKE SURE YOUR TEAM IS READY—CONSIDER ADDING ZURNAI TO YOUR AMBULANCE TOOLKIT TODAY

Click or scan the code to visit ZURNAI.com for important information and updates about ZURNAI

Order through Knoa Pharma Authorized Distributors
NDC 59011-962-01
More information available at 1-800-877-5666

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References: 1. ZURNAI™ (nalmefene injection) Auto-Injector Full Prescribing Information. Knoa Pharma LLC; 2026. **2.** Centers for Disease Control and Prevention. Provisional drug overdose data. CDC. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm. Published August 14, 2024. Accessed November 5, 2025. **3.** Friedman J, Hadland SE. The overdose crisis among US adolescents. *N Engl J Med*. 2024;390(2):97-100. doi:10.1056/NEJMp2312084. **4.** Palamar JJ, Ciccarone D, Rutherford C, Keyes KM, Carr TH, Cottler LB. Trends in seizures of powders and pills containing illicit fentanyl in the United States, 2018 through 2021. *Drug Alcohol Depend*. 2022;234:109398. doi:10.1016/j.drugalcdep.2022.109398. **5.** DEA. Fake pills fact sheet. www.dea.gov. https://www.dea.gov/sites/default/files/2024-11/DEA-OPCK_FactSheet_November_2024.pdf. Published November 2024. Accessed November 5, 2025. **6.** Stokes EK, Pickens CM, Wilt G, Liu S, David F. County-level social vulnerability and nonfatal drug overdose emergency department visits and hospitalizations, January 2018-December 2020. *Drug Alcohol Depend*. 2023;247:109889. doi:10.1016/j.drugalcdep.2023.109889. **7.** Skolnick P. Treatment of overdose in the synthetic opioid era. *Pharmacol Ther*. 2022;233:108019. doi:10.1016/j.pharmthera.2021.108019. **8.** National Institute on Drug Abuse. NIH HEAL Initiative. https://heal.nih.gov/about/research-plan. August 2024. Accessed November 5, 2025. **9.** Data on File. [PD-RPT-0643]. Stamford, CT: Knoa Pharma LLC. **10.** ZURNAI™ (nalmefene injection) Auto-Injector Instructions for Use. Knoa Pharma LLC.; 2026. **11.** Edinoff AN, Martinez Garza D, Vining SP, et al. New synthetic opioids: clinical considerations and dangers. *Pain Ther*. 2023;12(2):399-421. doi:10.1007/s40122-023-00481-6.

We are committed to maintaining the highest standards of sales and marketing practices, while continuing to advance the proper treatment of patients. If you have any questions or concerns with our sales and marketing practices, please contact us at 1-877-787-3831.

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