

PATIENT INFORMATION

ZURNAL™ (zur nye) (nalmeferene injection)

You and your family members or caregivers should read this Patient Information leaflet before an opioid emergency happens. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about ZURNAL?

ZURNAL is used to temporarily reverse the effects of opioid medicines. The medicine in ZURNAL is not expected to have an effect in people who are not taking opioid medicines. Always carry ZURNAL with you in case of an opioid emergency.

1. Use ZURNAL right away if you or your caregiver think signs or symptoms of an opioid emergency are present, even if you are not sure, because an opioid emergency can cause severe injury or death. Signs and symptoms of an opioid emergency may include:
 - unusual sleepiness and you are not able to awaken the person with a loud voice or by rubbing firmly on the middle of their chest (sternum).
 - breathing problems including slow or shallow breathing in someone difficult to awaken or who looks like they are not breathing.
 - the black circle in the center of the colored part of the eye (pupil) is very small, sometimes called “pinpoint pupils,” in someone difficult to awaken.
2. Family members, caregivers, or other people who may have to use ZURNAL in an opioid emergency should know where ZURNAL is stored and how to give ZURNAL before an opioid emergency happens. Make sure everyone reads the information contained in the carton as soon as you receive ZURNAL.
3. **Call 911 or get emergency medical help right away after giving the first dose of ZURNAL.** Rescue breathing or CPR (cardiopulmonary resuscitation) may be given while waiting for emergency medical help.
4. The signs and symptoms of an opioid emergency can return after ZURNAL is given. If this happens, give additional doses of ZURNAL every 2 to 5 minutes using a new ZURNAL auto-injector for each dose and watch the person closely until emergency help arrives.

What is ZURNAL?

- ZURNAL is a prescription medicine used in adults and children 12 years of age and older for the treatment of an opioid emergency such as an overdose or a possible opioid overdose with signs of breathing problems and severe sleepiness or not being able to respond.
- ZURNAL is to be given right away and does not take the place of emergency medical care. Get emergency medical help right away after giving the first dose of ZURNAL, even if the person wakes up.

It is not known if ZURNAL is safe and effective in children younger than 12 years of age for the emergency treatment of known or suspected opioid overdose.

Do not use ZURNAL if you are allergic to nalmeferene hydrochloride or any of the ingredients in ZURNAL. See the end of this Patient Information leaflet for a complete list of ingredients in ZURNAL.

Before using ZURNAL, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems.
- are pregnant or plan to become pregnant. It is not known if ZURNAL will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZURNAL passes into your breast milk.

Tell your healthcare provider about the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use ZURNAL?

Read the “Instructions for Use” at the end of this Patient Information leaflet for detailed information about the right way to use ZURNAL.

- Use ZURNAL exactly as prescribed by your healthcare provider.
- Each ZURNAL auto-injector contains only 1 dose of medicine and cannot be reused.
- The ZURNAL auto-injector is ready to use. Do not test or prime ZURNAL before use.
- ZURNAL should be injected into the muscle (intramuscular) or underneath the skin (subcutaneous) of the outer thigh. It can be injected through your clothing if needed.

What are the possible side effects of ZURNAL?

ZURNAL may cause serious side effects, including:

- **Sudden opioid withdrawal symptoms.** In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving ZURNAL and may include:
 - body aches
 - goose bumps
 - shivering or trembling
 - diarrhea
 - sweating
 - stomach cramping

- increased heart rate
- fever
- runny nose
- sneezing
- yawning
- nausea or vomiting
- nervousness
- restlessness or irritability
- weakness
- increased blood pressure

- **Risk of opioid overdose.** ZURNAL blocks the effects of opioids and may cause opioid withdrawal in someone who has been using opioids regularly. **Do not** take large amounts of opioids to try to overcome the opioid-blocking effects of ZURNAL. This could lead to an opioid overdose and death. Call 911 or get emergency medical help right away after using ZURNAL.

The most common side effects of ZURNAL include:

- feeling hot
- nausea
- headache
- dizziness
- chills
- vomiting
- feeling pain from things that are not usually painful (allodynia)
- irregular heartbeat (palpitations)
- ringing in the ear
- ear discomfort
- feeling abnormal
- burning sensation
- hot flush
- irritability

These are not all of the possible side effects of ZURNAL.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZURNAL?

- Store ZURNAL at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze or refrigerate.
- Store ZURNAL in a clean dry place. Protect from light.
- Keep ZURNAL in the carton until use.
- During storage, check ZURNAL through the viewing window of the auto-injector every 30 days. The liquid should be clear, colorless to light yellow. If the ZURNAL liquid is discolored, cloudy, or contains solid particles, replace it with a new ZURNAL.
- Check the expiration date. Replace ZURNAL before the expiration date.

Keep ZURNAL and all medicines out of the reach of children.

General information about the safe and effective use of ZURNAL.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ZURNAL for a condition for which it was not prescribed. You can ask your pharmacist or healthcare provider for information about ZURNAL that is written for health professionals.

What are the ingredients in ZURNAL?

Active ingredient: nalmefene

Inactive ingredients: hydrochloric acid to adjust pH, magnesium chloride, and water for injection.

ZURNAL is not made with natural rubber latex.

Manufactured for: Purdue Pharma L.P., Stamford, CT 06901-3431.

For more information, go to www.ZURNAL.com or call 1-888-726-7535.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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