teva | naloxone hydrochloride

nasal spray 4 mg

Quick Start Guide

Important: For use in the nose only.

Use Teva's Naloxone HCl Nasal Spray for known or suspected opioid overdose in adults and children.

Print this guide and keep it in a safe, convenient location so you are prepared for an opioid overdose emergency. Administer in accordance with the <u>Instructions for Use</u>. Talk to your healthcare provider if you have any questions about the use of Teva's Naloxone Hydrochloride Nasal Spray.

Teva's Naloxone HCl Nasal Spray should be used immediately if you or your caregiver *think* signs or symptoms of an opioid overdose emergency are present.

Check for these 3 signs of an opioid overdose emergency:

- unusual sleepiness, unconsciousness, or unresponsiveness
- breathing problems (slow or shallow breathing, or appearance of not breathing)
- very small, "pinpoint" pupils

If an opioid overdose is suspected...

STEP 1: Prepare to Administer Naloxone HCl Nasal Spray

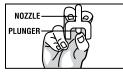
- Lay the person on their back to receive a dose of Teva's Naloxone HCl Nasal Spray.
- Remove Teva's Naloxone HCl Nasal Spray from the box. Peel back the tab with the circle to open Teva's Naloxone HCl Nasal Spray.





Note: Teva's Naloxone HCl Nasal Spray freezes at temperatures below 5°F. If this happens, the device will not spray and you should get emergency medical help right away. Do not wait for it to thaw. Teva's Naloxone HCl Nasal Spray may still be used if it has been thawed after being previously frozen.

• Hold Teva's Naloxone HCl Nasal Spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.



STEP 2: Administer Naloxone HCl Nasal Spray

- Tilt the person's head back and provide support under the neck with your hand.
- Insert the tip of the nozzle into **one nostril** until your fingers on either side of the nozzle are against the bottom of the person's nose.
- Press the plunger firmly to give the dose of Teva's Naloxone HCl Nasal Spray. Then remove the plunger after giving the dose.



STEP 3: Get Emergency Help and Monitor

- After using Teva's Naloxone HCl Nasal Spray, get emergency medical help right away.
- Move the person on their side (recovery position) after giving the dose.



- Watch the person closely until emergency personnel arrive.
- If the person does not respond or relapses into respiratory depression, re-administer another dose of Teva's Naloxone HCl Nasal Spray in alternating nostrils every 2-3 minutes until the person responds or emergency personnel arrive.
- Each Naloxone HCl Nasal Spray device contains a single dose and cannot be reused.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about naloxone hydrochloride nasal spray?

Naloxone hydrochloride nasal spray is used to temporarily reverse the effects of opioid medicines. The medicine in naloxone hydrochloride nasal spray has no effect in people who are not taking opioid medicines. Always carry naloxone hydrochloride nasal spray with you in case of an opioid emergency.

- 1. Use naloxone hydrochloride nasal spray 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



IMPORTANT SAFETY INFORMATION (CONTINUED)

- 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 naloxone hydrochloride nasal spray in an opioid emergency should know where naloxone hydrochloride nasal spray is stored and how to give naloxone hydrochloride before an opioid emergency happens.
- 3. Get emergency medical help right away after giving the first dose of naloxone hydrochloride nasal spray. 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 naloxone hydrochloride nasal spray is given. If this happens, give another dose after 2 to 3 minutes using a new naloxone hydrochloride nasal spray and watch the person closely until emergency help is received.

Who should not use naloxone hydrochloride nasal spray?

Do not use naloxone hydrochloride nasal spray if you are allergic to naloxone hydrochloride or any of the ingredients in naloxone hydrochloride nasal spray. See the end of the Patient Information Leaflet found at the end of the Prescribing Information for a complete list of ingredients in naloxone hydrochloride nasal spray.

What should I tell my healthcare provider before using naloxone hydrochloride nasal spray?

Before using naloxone hydrochloride nasal spray, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- are pregnant or plan to become pregnant. Use of naloxone hydrochloride nasal spray may cause withdrawal symptoms in your unborn baby. Your unborn baby should be examined by a healthcare provider right away after you use naloxone hydrochloride nasal spray.
- are breastfeeding or plan to breastfeed. It is not known if naloxone hydrochloride 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.

What are the possible side effects of naloxone hydrochloride nasal spray?

Naloxone hydrochloride nasal spray 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 naloxone hydrochloride nasal spray and may include: body aches, diarrhea, increased heart rate, fever, runny nose, sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, stomach cramping, weakness, or increased blood pressure.

In infants under 4 weeks old who have been receiving opioids regularly, sudden opioid withdrawal may be life-threatening if not treated the right way. Signs and symptoms include: seizures, crying more than usual, and increased reflexes.

These are not all of the possible side effects of naloxone hydrochloride nasal spray. Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

APPROVED USES

What is naloxone hydrochloride nasal spray?

- Naloxone hydrochloride nasal spray is a prescription medicine used 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.
- Naloxone hydrochloride nasal spray 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 naloxone hydrochloride nasal spray, even if the person wakes up.
- Naloxone hydrochloride nasal spray is safe and effective in children for known or suspected opioid overdose.

Please read the Patient Information Leaflet in the full Prescribing Information.

