

Frequently Asked Questions about NARCAN[®] (naloxone HCl) Nasal Spray Shelf-Life Extension and Updated Storage Conditions

What is NARCAN[®] Nasal Spray?

- NARCAN[®] Nasal Spray is a prescription medicine used for the treatment of a known or suspected opioid overdose emergency with signs of breathing problems and severe sleepiness or not being able to respond.
- NARCAN[®] 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 NARCAN[®] Nasal Spray, even if the person wakes up.

Please see Important Safety Information below

Who should not use NARCAN[®] Nasal Spray?

Do not use NARCAN[®] Nasal Spray if you are allergic to naloxone hydrochloride or any of the ingredients in NARCAN[®] Nasal Spray.

What is the new shelf life of NARCAN[®] Nasal Spray?

NARCAN[®] expiration will now be changed from 24 to 36 months.

Will current, on-market NARCAN[®] Nasal Spray's expiration be extended an additional 12 months?

The FDA has approved the 36-month shelf-life after completing a comprehensive review of data which included all versions of NARCAN[®]. Since this study was conducted using all versions of NARCAN[®], any product previously released with a 24-month shelf life can now be extended for an additional 12 months.

What are the updated storage conditions for NARCAN[®] Nasal Spray?

Current Label: Store NARCAN[®] Nasal Spray in the blister and cartons provided.

Store at controlled room temperature 68°F to 77 °F (20°C to 25°C).

Excursions permitted between 41°F to 104°F (5°C to 40°C).

Do not freeze or expose to excessive heat above 104°F (40°C). Protect from light. NARCAN[®] Nasal Spray freezes at temperatures below 5°F (-15°C). If this happens, the device will not spray. Leave the device at room temperature for 15 minutes to thaw the medicine before use.

New Label: Store NARCAN[®] Nasal Spray in the blister and cartons provided.

Store below 77°F (25°C). Excursions permitted up to 104°F (40°C).

Do not freeze or expose to excessive heat above 104°F (40°C). Protect from light.

NARCAN[®] Nasal Spray freezes at temperatures below 5°F (-15°C). If this happens, the device will not spray. If

NARCAN[®] Nasal Spray is frozen and is needed in an emergency, do NOT wait for NARCAN[®] Nasal Spray to thaw.

Get emergency medical help right away. However, NARCAN[®] Nasal Spray may be thawed by allowing it to sit at room temperature for 15 minutes, and it may still be used if it has been thawed after being previously frozen.

Important Safety information for NARCAN[®] Nasal Spray

What is the most important information I should know about NARCAN[®] Nasal Spray?

NARCAN[®] Nasal Spray is used to temporarily reverse the effects of opioid medicines. The medicine in NARCAN[®] Nasal Spray has no effect in people who are not taking opioid medicines. Always carry NARCAN[®] Nasal Spray with you in case of an opioid overdose.

1. Use NARCAN[®] Nasal Spray right away if you or your caregiver think signs or symptoms of an opioid overdose are present, even if you are not sure, because an opioid overdose can cause severe injury or death. Signs and symptoms of an opioid overdose 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 NARCAN® Nasal Spray in an opioid overdose should know where NARCAN® Nasal Spray is stored and how to give NARCAN® Nasal Spray before an opioid overdose happens.
 3. **Get emergency medical help right away after giving the first dose of NARCAN® 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 overdose can return after NARCAN® Nasal Spray is given. If this happens, give another dose after 2 to 3 minutes using a new NARCAN® Nasal Spray device and watch the person closely until emergency help is received.

What should I tell my healthcare provider before using NARCAN® Nasal Spray?

Before using NARCAN® 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 NARCAN® 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 NARCAN® Nasal Spray.
- are breastfeeding or plan to breastfeed. It is not known if NARCAN® Nasal Spray passes into your breast milk.

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

What are the possible side effects of NARCAN® Nasal Spray?

NARCAN® Nasal Spray may cause serious side effects, including:

Sudden opioid withdrawal symptoms which can be severe. In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving NARCAN® 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
- increased blood pressure

Some patients may show aggressive behavior upon abrupt reversal of an opioid overdose.

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 NARCAN® Nasal Spray. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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