



APRIL 5, 2023

## FDA Approves Narcan Nasal Spray for First Over-the-Counter Sales

### Allen Research Endowment Recommended OTC Narcan in Comment Letter to FDA

- The Allen Research Endowment, a 501(c)(3) tax-exempt organization focused on non-opioid, non-addictive pain management solutions, announced that in March 2023, the U.S. Food and Drug Administration (FDA) **approved Narcan nasal spray** for **over-the-counter sales** without a prescription. Narcan is a brand for naloxone hydrochloride.
- The Allen Research Endowment **provided a comment letter** to the FDA’s Office of Regulatory Policy for Naloxone Federal Register Notice 2022-N-2673 recommending that the FDA urgently take action to reduce ongoing Opioid overdose deaths in the U.S and to approve naloxone for over-the-counter sales.
- According to the Allen Research Endowment, many people do not realize that opioids continue to be the “**standard of care**” at hospitals for pain management. Unfortunately, until this changes, opioid related addiction and overdoses will continue. Naloxone is a life-saving medication that rapidly reverses an opioid related overdose.

**ABOUT NALOXONE AND NARCAN NASAL SPRAY**

For general answers about naloxone and Narcan from the CDC, National Institutes of Health, and other government agencies, please see below. Please check with your healthcare provider for professional answers to your specific situation.

**Q1. What is naloxone?**

A1. It is a life-saving medication that can reverse the effects of an overdose from opioids including heroin and fentanyl.

**Q2. What is the shelf-life of naloxone?**

A2. Depending on the specific brand, in general, about 2 - 3 years.

**Q3. What is the expected cost of Narcan nasal spray?**

A3. For two doses, expect a price around \$50.

**Q4. When and where can I buy Narcan?**

A4. Expect OTC Narcan nasal spray to be available in August 2023 at pharmacies, grocery stores, gas stations and online.

**Q5. How do you administer Narcan nasal spray?**

- A5.
- Call 911 and while waiting for medical professionals to arrive, tilt overdosing person's head back as they lay down on back to open nasal channels
  - Remove wrapper of nasal spray, place tip of nasal spray into one of the nostrils of the person,
  - Hold the nasal spray with your hand, and with your thumb - push out the spray into the nostril
  - Wait 2-3 minutes for the person to start breathing again
  - If the person is still not breathing, administer another dose – into the other nostril. Repeat.

**Q6. What should I do if overdosing person initially recovers, then later, starts overdosing again?**

A6. Since the opioid's effective time period is longer than Narcan's, repeat the Narcan spray process again into the overdosing person's nostrils as described above.

**Q7. How do I know when someone is overdosing?**

A7. First, don't leave the person alone. If they are conscious, walk them around, keep them awake and monitor their breathing.

Then, look for any of the following signs:

- Loss of consciousness
- Awake but unable to talk or respond to stimulus (i.e. to shouting or loud handclaps)
- Breathing is very slow, erratic or has stopped
- Vomiting
- Body is very limp
- Fingernails and lips turn blue or purplish black
- Pulse (heartbeat) is slow, erratic or not there at all.

**Q8. Is Narcan nasal spray easy to use?**

A8. Yes. Its use is similar to a typical nasal spray.

**Q9. Can I use Narcan on myself?**

A9. No, Narcan cannot be used prior to taking drugs. Also, when a person overdoses, they cannot breathe and will be unconscious.

**Q10. Can I keep Narcan nasal spray in my car?**

A10. In general, Narcan nasal spray can be kept in places with a temperature range of 59-86 °F and not in direct sunlight.

SOURCES: CDC, NATIONAL INSTITUTES OF HEALTH, ALLEN RESEARCH ENDOWMENT, INC

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