

# EMERGENT

## Emergent BioSolutions Announces FDA Approval of NARCAN® (naloxone HCl) Nasal Spray Shelf Life Extension to 36 Months

August 17, 2020

GAITHERSBURG, Md., Aug. 17, 2020 (GLOBE NEWSWIRE) -- Emergent BioSolutions Inc. (NYSE: EBS) today announced that the U.S. Food and Drug Administration (FDA) has approved the extension of the shelf life of NARCAN® (naloxone HCl) Nasal Spray from 24 months to 36 months. Narcan Nasal Spray was the first intranasal form of naloxone approved by FDA and Health Canada for the emergency treatment of known or suspected opioid overdose.

"Emergent is pleased to receive FDA approval of the shelf life extension for NARCAN® Nasal Spray," said Doug White, SVP and devices business unit head at Emergent. "This is an example of our continued efforts to innovate and improve product features designed to address the needs of patients, consumers, health care providers, pharmacists, and first responders."

In early July, the company launched the Generation II NARCAN® Nasal Spray device, which is identified by a red plunger and enhances temperature excursions and storage below 25°C.

### About NARCAN® Nasal Spray 4mg

NARCAN® Nasal Spray 4mg is the first FDA-approved, needle-free presentation of naloxone for the emergency treatment of a known or suspected opioid overdose. It does not require assembly or any specialized medical training and is also the highest concentrated dose of intranasal naloxone currently available. NARCAN® Nasal Spray is not a substitute for emergency medical care, and additional doses of NARCAN® Nasal Spray may be required until emergency medical assistance arrives. Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

Please see Indications and Important Safety Information below.

### INDICATION AND IMPORTANT SAFETY INFORMATION FOR NARCAN NASAL SPRAY

#### What is NARCAN Nasal Spray?

- NARCAN Nasal Spray is a prescription medicine used for the emergency 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.

NARCAN Nasal Spray is safe and effective in children for known or suspected opioid overdose.

#### 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 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 <http://www.fda.gov/medwatch>.

NNS CON ISI 07/2020

Please see [full Prescribing Information](#).

For additional information on NARCAN<sup>®</sup> Nasal Spray, please visit [www.NARCAN.com](http://www.NARCAN.com).

#### **About Emergent BioSolutions**

Emergent BioSolutions is a global life sciences company whose mission is to protect and enhance life. Through our specialty products and contract development and manufacturing services, we are dedicated to providing solutions that address public health threats. Through social responsibility, we aim to build healthier and safer communities. We aspire to deliver peace of mind to our patients and customers so they can focus on what's most important in their lives. In working together, we envision protecting or enhancing 1 billion lives by 2030.

#### **Investor Contact:**

Robert G. Burrows  
Vice President, Investor Relations  
240-631-3280  
[BurrowsR@ebsi.com](mailto:BurrowsR@ebsi.com)

#### **Media Contact:**

Miko B. Neri  
Senior Director, Global Communications & Public Affairs  
240-631-3392  
[NeriM@ebsi.com](mailto:NeriM@ebsi.com)

Emergent BioSolutions<sup>®</sup>, NARCAN<sup>®</sup> and any and all Emergent BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. PP-NAR4-US-00362 Aug 2020



Source: Emergent BioSolutions