

## **PART III: PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **NARCAN NASAL SPRAY** naloxone hydrochloride nasal spray

2 mg and 4 mg

Read this carefully before administering **NARCAN NASAL SPRAY** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **NARCAN NASAL SPRAY**.

#### **Serious Warnings and Precautions**

- Before administering **NARCAN NASAL SPRAY**, call 911 for emergency medical help. Do this immediately if you suspect or are aware of an opioid overdose.
- Make sure to watch the person who received **NARCAN NASAL SPRAY**. You may need to give additional doses of **NARCAN NASAL SPRAY** until emergency medical help arrives.
- You may need to help the person who received **NARCAN NASAL SPRAY**. The patient may have a reaction such as becoming aggressive, shaking and/or vomiting. You will need to pay special attention when giving **NARCAN NASAL SPRAY** to a newborn who is less than four weeks old or a pregnant woman. Some of these reactions can be life-threatening for a newborn or a fetus.

#### **What is **NARCAN NASAL SPRAY** used for?**

**NARCAN NASAL SPRAY** is used to treat someone who has overdosed on opioids. **NARCAN NASAL SPRAY** can be used by anyone to reverse the effects of the overdose until medical help arrives. Signs of an opioid overdose include:

- trouble breathing or not breathing
- extreme drowsiness
- pale and clammy skin
- slow or no heartbeat
- passing out
- unable to be woken up by touch, shaking of shoulders or shouting
- very small pupils, like a pinpoint

**How does NARCAN NASAL SPRAY work?**

Opioid drugs work by acting on specific receptors found in the brain and in the nervous system. When these drugs attach to those receptors, they reduce the amount of pain felt. Taking too many opioids can lead to an overdose and that can stop someone from breathing. The person may also experience other symptoms. NARCAN NASAL SPRAY stops the opioids from being attached to the receptors and this reverses the effects and symptoms of the overdose.

**What are the ingredients in NARCAN NASAL SPRAY?**

Medicinal ingredient: naloxone hydrochloride

Non-medicinal ingredients: benzalkonium chloride, disodium ethylenediaminetetraacetate, sodium chloride, hydrochloric acid and purified water.

**NARCAN NASAL SPRAY comes in the following dosage forms:**

Each NARCAN NASAL SPRAY device contains either 2 mg or 4 mg in 0.1mL of solution.

**Do not use NARCAN NASAL SPRAY if:**

- you are sure that the patient is allergic to naloxone hydrochloride or to any of the ingredients in NARCAN NASAL SPRAY.

**Warnings you should know about:**

**Non-opioid overdoses:** NARCAN NASAL SPRAY does not reduce the effects of an overdose caused by other drugs such as:

- barbiturates
- benzodiazepines
- psychostimulants (for example: cocaine, amphetamines or methylphenidate)
- alcohol
- anesthetics
- sedatives.

Giving NARCAN NASAL SPRAY to a person because of a non-opioid overdose is unlikely to cause more harm.

**Return of Opioid Overdose Symptoms:** It may be possible that the signs of an opioid overdose return after a dose of NARCAN NASAL SPRAY has been given. For example, a patient who responded to the first dose may experience a return of the signs of an overdose.

You should:

- monitor the patient.
- give repeated doses of NARCAN NASAL SPRAY to the patient if needed and available.
- lie the patient on their side to help them have a clear airway.
- perform artificial respiration or cardiac massage, only if needed and if you know how.
- wait for emergency medical help to arrive.

**Acute Opioid Withdrawal Syndrome:**

- NARCAN NASAL SPRAY should be given with caution to a patient who may be or who is addicted to opioids.
- After receiving NARCAN NASAL SPRAY, the patient may go into Acute Opioid Withdrawal Syndrome. Symptoms include:
  - shaking or having seizures
    - move away any sharp and dangerous objects to prevent injury.
    - do not try to hold the patient down.
  - vomiting
    - place the patient on their side to prevent choking if they vomit.
  - pain
  - fever
  - restlessness
  - irritability
  - aggressive behavior
  - sweating
  - yawning
  - weakness
  - shivering
  - trembling
  - increased blood pressure
- Acute Opioid Withdrawal Syndrome can be life-threatening for a newborn. Symptoms in newborns also include:
  - excessive crying
  - twitching and hyperactive reflexes.

**Heart problems:**

Naloxone is the active ingredient in NARCAN NASAL SPRAY. After using naloxone some patients had:

- a heart attack
- an increased heart rate
- an irregular heartbeat.

These side effects were rare. It is not known if the reactions were caused by naloxone or by the overdose.

**Patients who have had surgery:** The following occurred when some patients who had a recent surgery received naloxone:

- high and low blood pressure
- increased heart rate
- rapid irregular heartbeat
- a build-up of fluid in the lungs
- in rare cases, cardiac arrest

These side effects were rare. It is not known if the reactions were caused by naloxone or by the overdose.

**Patients with nasal problems:** It is not known if having any nasal problems will impact how NARCAN NASAL SPRAY works. Examples of nasal problems include a blocked or runny nose or nasal polyps. If NARCAN NASAL SPRAY is the only medication available to treat an opioid overdose, it should always be used.

**Pregnant Women:** NARCAN NASAL SPRAY should only be used in pregnant women when clearly needed.

#### **How to Administer NARCAN NASAL SPRAY:**

##### **Important Points:**

- NARCAN NASAL SPRAY is for use in the nose only.
- Do not test the NARCAN NASAL SPRAY device. Keep NARCAN NASAL SPRAY in the package until it is needed.
- Each NARCAN NASAL SPRAY device contains only 1 dose and cannot be reused.
- NARCAN NASAL SPRAY is not a substitute for emergency medical care. Always call 911 before administering NARCAN NASAL SPRAY.

##### **Dose:**

- NARCAN NASAL SPRAY is available as a 2 mg or 4 mg nasal spray device.
- The lowest available strength should be used as the initial dose.
- The pharmacist may recommend using an alternate form of naloxone in newborns or children under two years old. This is because smaller doses can be given with the injectable form of naloxone.

## **Step 1: Identify Opioid Overdose & Call for Emergency Medical Help.**

### **Check for signs of an opioid overdose:**

- Person **DOES NOT** wake up after you shout, shake their shoulders, or firmly rub the middle of their chest.
- Breathing is very slow, irregular or has stopped.
- Center part of their eye is very small, like a pinpoint.



**Call 911** or ask someone to call for you.

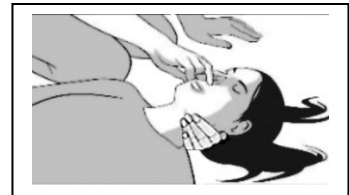
**Lay the person on their back.**

## **Step 2: Give NARCAN NASAL SPRAY**

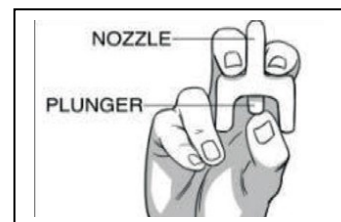
**Remove device from Packaging. Do not test the device.**  
There is only one dose per device.



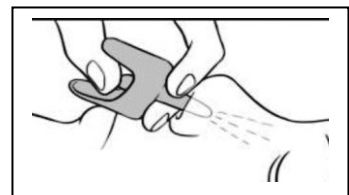
**Tilt the person's head back** and provide support under their neck with your hand.



**Hold the device** with your thumb on the bottom of the plunger. Put your first and middle fingers on either side of the nozzle.



**Gently insert the tip of the nozzle into one nostril.**  
Your fingers should be right up against the nose. If giving to a child, make sure the nozzle seals the nostril.



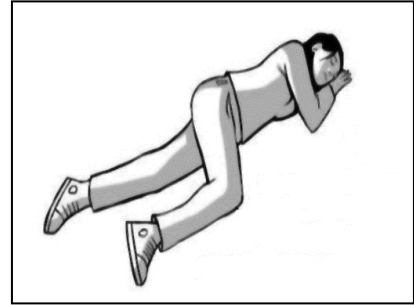
**Press the plunger firmly** with your thumb to give the dose.

**Remove the device** from the nostril.

### **Step 3: Evaluate and support**

**Move** the person on their side (recovery position). Watch them closely.

**Give a second dose after 2 to 3 minutes** if the person has not woken up or their breathing is not improved. **Alternate nostrils with each dose.**



You can give a dose every 2 to 3 minutes, if more are available and are needed.

**Perform artificial respiration or cardiac massage** until emergency medical help arrives, if you know how and if it is needed.

### **What are possible side effects from using NARCAN NASAL SPRAY?**

- Swelling in the nose
- Dryness in the nose
- Congested nose
- Runny nose
- Yawning
- Nervousness
- Pain
- Aggressive behaviors, irritability, restlessness, agitation
- Blood pressure increased
- Increased heart rate
- Nausea, vomiting
- Diarrhea, abdominal cramps
- Shivering, chills, tremors, trembling
- Fever
- Sweating
- Weakness
- Seizures
- Shaking
- Muscle spasms
- Dizziness
- Headache

911 should be called before administering NARCAN NASAL SPRAY. This will ensure the patient gets the help needed to deal with any overdose symptoms and any side effects.

## Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

### 3 ways to report:

- Online at [MedEffect \(http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php\)](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- Keep NARCAN NASAL SPRAY in its box until ready to use.
- Store between 15°C to 25°C.
  - NARCAN NASAL SPRAY may be stored for short periods up to 40°C.
  - Do not store NARCAN NASAL SPRAY in the car on hot summer days.
  - Do not freeze or leave NARCAN NASAL SPRAY in a car during the winter.
  - NARCAN NASAL SPRAY may not be as effective if it is not stored properly. If NARCAN NASAL SPRAY gets frozen or is stored at 40°C for long periods of time, you should replace it. Only discard the NARCAN NASAL SPRAY once you have a replacement for it. If you don't replace NARCAN NASAL SPRAY before it is needed, it is better to use it, even if it hasn't been stored properly.
- Store in a dark place and protect from light.
- Replace NARCAN NASAL SPRAY before the expiration date on the box.
  - If only expired NARCAN NASAL SPRAY is available, it should be used in an overdose situation.
- Keep out of reach and sight of children.

**If you want more information about NARCAN NASAL SPRAY:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website \(http://hc-sc.gc.ca/index-eng.php\)](http://hc-sc.gc.ca/index-eng.php); the manufacturer's website [www.adaptpharma.com](http://www.adaptpharma.com) or by calling 1-844-898-0657.

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