

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TEVA-NALOXONE NASAL SPRAY

naloxone hydrochloride nasal spray

4 mg

Read this carefully before administering TEVA-NALOXONE 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 TEVA-NALOXONE NASAL SPRAY.

Serious Warnings and Precautions

- Before administering TEVA-NALOXONE 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 TEVA-NALOXONE NASAL SPRAY. You may need to give additional doses of TEVA-NALOXONE NASAL SPRAY until emergency medical help arrives.
- You may need to help the person who received TEVA-NALOXONE 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 TEVA-NALOXONE 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 fetus.

What is TEVA-NALOXONE NASAL SPRAY used for?

TEVA-NALOXONE NASAL SPRAY is used to treat someone who has overdosed on opioids. TEVA-NALOXONE 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 TEVA-NALOXONE 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. TEVA-NALOXONE 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 TEVA-NALOXONE NASAL SPRAY?

Medicinal ingredient: naloxone hydrochloride

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

TEVA-NALOXONE NASAL SPRAY comes in the following dosage forms:

Each TEVA-NALOXONE NASAL SPRAY device contains 4 mg of naloxone hydrochloride in 0.1 mL of solution.

Do not use TEVA-NALOXONE NASAL SPRAY if:

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

Warnings you should know about:

Non-opioid overdoses: TEVA-NALOXONE 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 TEVA-NALOXONE 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 TEVA-NALOXONE 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 TEVA-NALOXONE 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:

- TEVA-NALOXONE NASAL SPRAY should be given with caution to a patient who may be or who is addicted to opioids.
- After receiving TEVA-NALOXONE 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 TEVA-NALOXONE 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 TEVA-NALOXONE NASAL SPRAY works. Examples of nasal problems include a blocked or runny nose or nasal polyps. If TEVA-NALOXONE NASAL SPRAY is the only medication available to treat an opioid overdose, it should always be used.

Pregnant Women: TEVA-NALOXONE NASAL SPRAY should only be used in pregnant women when clearly needed.

How to Administer TEVA-NALOXONE NASAL SPRAY:

Important Points:

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

Dose:

- TEVA-NALOXONE NASAL SPRAY is available as a 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
- Centre part of their eye is very small, like a pinpoint.

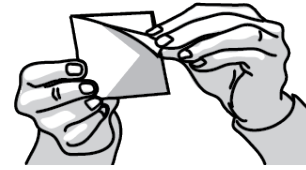


Call 911 or ask someone to call for you.

Lay the person on their back.

Step 2: Give TEVA-NALOXONE NASAL SPRAY

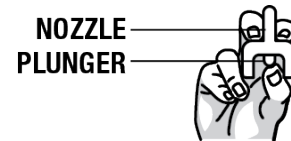
Remove device from packaging. **Do not test the device.** There is only one dose per device.



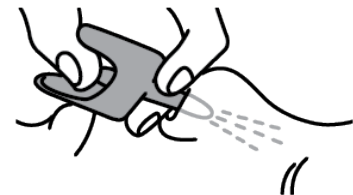
Tilt the person's head back and provide support under their neck with your hand.



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.



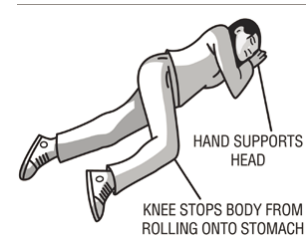
Press the plunger firmly with your thumb to give the dose.

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 know how and if it is needed.

What are possible side effects from using TEVA-NALOXONE NASAL SPRAY?

- Swelling in the nose
- Dryness in the nose
- Congested nose
- Runny nose

- Yawning
- Nervousness
- Pain
- Aggressive behaviours, 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 TEVA-NALOXONE 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 report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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:

- Store TEVA-NALOXONE NASAL SPRAY in the blister and cartons provided.
- Store between 15°C to 30°C. Can be stored up to 40°C only for short periods of time. Do not freeze or expose to excessive heat above 40°C.
- TEVA-NALOXONE NASAL SPRAY freezes at temperatures below -15°C. If this happens, the device will not spray. If TEVA-NALOXONE NASAL SPRAY is frozen and is needed in an emergency, do NOT wait for TEVA-NALOXONE NASAL SPRAY to thaw. Get emergency medical help right away.
- You can thaw TEVA-NALOXONE NASAL SPRAY by allowing it to sit at room temperature for 15 minutes. You can still use it if it has been thawed after being previously

frozen.

- Replace TEVA-NALOXONE NASAL SPRAY before the expiration date on the box.
 - If only expired TEVA-NALOXONE 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 TEVA-NALOXONE 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 (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website <http://www.tevacanada.com>; or by calling 1-800-268-4127 ext. 3; or email druginfo@tevacanada.com.

This leaflet was prepared by Teva Canada Limited, Toronto, Ontario M1B 2K9

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