How to reverse an opioid overdose with Nyxoid® Nasal Spray.[1]

NYXOID® naloxone

Who is Nyxoid® for?

Nyxoid® is a single-dose nasal spray for emergency use to reverse an overdose of opioid drugs (such as heroin, methadone, fentanyl, oxycodone, buprenorphine or morphine). Each pack contains 2 devices (one spray each).

Nyxoid® is not a substitute for emergency medical care.

When carried by people at risk of overdosing on an opioid, carers such as family of friends should know where to find Nyxoid® in case of emergency.

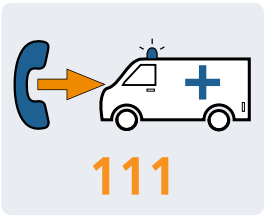
What to do if you think there's been an opioid overdose

1 Check for signs of overdose

- **Approach with care**. Check for dangers, such as injecting materials that might be lying around.
- **Check for a response**, to see if the person is conscious.
  - talk loudly into their ear
  - gently shake their shoulders
  - rub their breastbone (sternum)
  - pinch their ear or the bed of their fingernail
- **Clear the mouth and nose** of any blockages
- **Check airways and breathing**:
  - is the chest moving?
  - can you hear breathing sounds?
  - can you feel their breath on your cheek?
- **Check other signs of overdose**:
  - slow, uneven breathing or no breathing
  - snoring, gasping or gulping
  - blue or purple fingernails or lips

2 Call an ambulance immediately – Dial 111

Always call for emergency services immediately, even if the person wakes up.



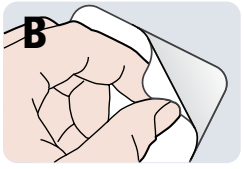
! Nyxoid® is not a substitute for emergency medical care or basic life support (such as CPR, including rescue breathing.*)

- Put your phone on loudspeaker, to keep your hands free
- **Give emergency services as much information as you can:**
- your exact location (if known)
- what substances you think the person may have taken
- whether they are conscious and breathing
- that you plan to give Nyxoid® Nasal Spray

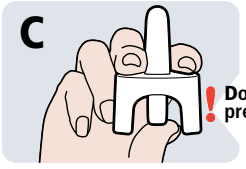
3 Give 1 spray of Nyxoid® Nasal Spray

Each nasal spray contains **one dose only**.

Lay the person on their back. Support the back of the neck, and let the head tilt back. Clear away anything you see blocking their nose.

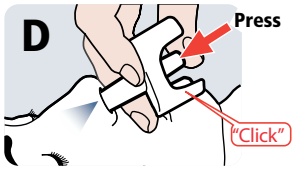


Peel off the back of the Nyxoid® container. Remove the nasal spray and place it within easy reach.



Hold the spray as shown — first two fingers either side of the nozzle, thumb ready to push the plunger.

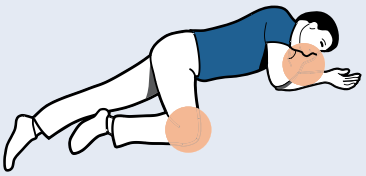
! Don't press to prime or test before use.



Gently insert the spray nozzle into **one nostril. Press firmly** on the plunger **until it clicks** and gives the dose. **Remove the nozzle** from the nostril. If possible, note which nostril you used.

4 Put into recovery position

Hand supports head



Top leg bent at hip and knee.

Roll the patient on their side with mouth open pointing towards the ground and ensure the airways remain open.

5 Monitor until help arrives

The patient must be monitored closely as the effect of some opioids can be longer than the effect of Nyxoid®. This could lead to recurrence of respiratory depression.

- **Stay with the person**. Watch for an improvement in breathing, alertness, and their response to sound and touch.
- Be aware - even if they wake up, they may become unconscious again, and stop breathing.

6 No response? Give 2nd dose

- If there's no improvement after 2–3 minutes, or if overdose symptoms come back, **use a new Nyxoid® nasal spray in the other nostril**. (Repeat Step 3). You can do this while the person is in the recovery position.
- If the person is unconscious and not breathing normally, give basic life support (such as CPR, including rescue breathing*) if you are trained to.

7 Take care for your own safety

Nyxoid® can cause **acute withdrawal symptoms** if the person is dependent on opioid drugs.

Symptoms can include:

- body aches and cramps
- vomiting, nausea, diarrhoea
- fever, runny nose or sneezing
- sweating, shivering or trembling
- nervousness or irritability

! **Take care. A person treated with Nyxoid® may experience acute withdrawal symptoms which may cause them to become irritable or aggressive.**

8 When the ambulance arrives

- **Immediately tell them what has happened and that you have given Nyxoid®.** Give them any used Nyxoid® spray devices.

  If you forget to give the used sprays to the paramedics, pass them to a healthcare professional or pharmacist, and arrange for replacements. Never throw away the sprays in water waste or household waste.

If you carry Nyxoid®

Set an alert in your calendar for 1 month before your Nyxoid® is due to expire. Then arrange for a replacement.

NYXOID® - naloxone hydrochloride dihydrate - **PRESCRIPTION MEDICINE**
Presentation: NYXOID® is a nasal spray containing 1.8mg naloxone (as hydrochloride dihydrate).
Indications: NYXOID is intended as part of the emergency treatment for known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression. NYXOID is indicated in adults and adolescents aged 14 years of age and over.
Contraindications: Hypersensitivity to the active substance or to any of the excipients (naloxone, sodium citrate dihydrate, sodium chloride, hydrochloric acid, sodium hydroxide, purified water)
Special warnings and precautions for use: NYXOID should only be made available once the suitability and competence of an individual to administer naloxone in the appropriate circumstances has been established. NYXOID is not a substitute for emergency medical care and may be used instead of intravenous (IV) injection, when IV access is not immediately available. *The importance of seeking medical assistance:* NYXOID is intended as part of an emergency treatment and the patient/carer should be advised to seek medical help immediately. *Monitoring of the patient for a response:* Patients who respond satisfactorily to naloxone must be closely monitored. The effect of some opioids can be longer than the effect of naloxone which could lead to reoccurrence of respiratory depression and therefore further doses of naloxone may be required. *Opioid withdrawal syndrome:* Receiving naloxone can lead to a rapid reversal of the opioid effect which can cause an acute withdrawal syndrome in such patients. Patients who are receiving opioids for the relief of chronic pain may experience pain and opioid withdrawal symptoms when naloxone is administered. *Effectiveness of naloxone:* Reversal of buprenorphine-induced respiratory depression may be incomplete. If an incomplete response occurs, respiration should be mechanically assisted. Intranasal absorption and efficacy of naloxone can be altered in patients with damaged nasal mucosa and septal defects. *Paediatric population:* Opioid withdrawal may be life-threatening in neonates if not recognised and properly treated and may include the following signs and symptoms: convulsions, excessive crying and hyperactive reflexes. *Pregnancy:* There are no adequate data from the use of naloxone in pregnant women. NYXOID should not be used during pregnancy unless the clinical condition of the women requires treatment with naloxone. *Breastfeeding:* It is unknown whether naloxone is excreted in human breast milk and it has not been established whether infants who are breast-fed are affected by naloxone. Caution should be exercised when naloxone is administered to a breast-feeding mother but there is no need to discontinue breast-feeding. Breast-fed babies from mothers who have been treated with NYXOID should be monitored to check for sedation or irritability.
Interactions: Naloxone elicits a pharmacological response due to the interaction with opioids and opioid agonists. When administered to opioid dependent subjects, naloxone can cause acute withdrawal symptoms in some individuals. Hypertension, cardiac arrhythmias, pulmonary oedema and cardiac arrest have been described, more typically when naloxone is used post-operatively. Administration of NYXOID may decrease the analgesic effects of opioids used primarily to provide pain relief, due to its antagonistic properties.
Dose and administration: Nasal use only. One spray of NYXOID into one nostril. Re-administer NYXOID, using a new NYXOID container, into the other nostril after 2 to 3 minutes if the patient does not respond or responds and then relapses into respiratory depression. Further doses may be given every 2 to 3 minutes in alternate nostrils if needed until further assistance is available. NYXOID spray should be administered as soon as possible to avoid damage to the central nervous system or death. NYXOID contains only one dose and therefore it must not be primed or tested prior to administration. The device is ready for use. If an overdose is suspected, call for emergency medical assistance immediately. NYXOID is NOT a substitute for emergency medical care.
Adverse Effects: *Very Common:* Nausea. *Common:* Dizziness, Headache, Tachycardia, Hypotension, Hypertension, Vomiting. *Uncommon:* Tremor, Arrhythmia, Bradycardia, Hyperventilation, Diarrhoea, Dry mouth, Hyperhidrosis, Drug withdrawal syndrome (in patients dependent on opioids). *Very Rare:* Hypersensitivity, Anaphylactic shock, Cardiac fibrillation, Cardiac arrest, Pulmonary oedema, Erythema multiforme

Pharmaco (NZ) Ltd, Auckland. Data Sheet Feb 2018

NYXOID is an unfunded medicine, a prescription charge will apply.

Prior to prescribing or for further information please consult the manufacturer's full data sheet available at www.medsafe.govt.nz.

For Consumers: Nyxoid is a PRESCRIPTION MEDICINE. Use strictly as directed. If symptoms continue or you have side effects, see your doctor, pharmacist or healthcare professional. Further information on the risks and benefits of this medicine please contact your doctor, pharmacist or healthcare professional or access the Consumer Medicines Information available at www.medsafe.govt.nz
TAPS NA 11113

*For more information about training in basic life support, refer to the New Zealand Resuscitation Council www.nzrc.org.nz

Reference: 1. Nyxoid Nasal Spray Data Sheet, February 2019.® NYXOID is a registered trade mark of MUNDIPHARMA.

Pharmaco Medical + Emergency

FM0147 July 2019