NYXOID® nasal spray

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NYXOID?

NYXOID contains the active ingredient Naloxone. NYXOID is a nasal spray used as part of the emergency treatment of opioid overdose or possible opioid overdose.

For more information, see Section 1. Why am I using NYXOID? in the full CMI.

2. What should I know before I use NYXOID?

Do not use if you have ever had an allergic reaction to Naloxone or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use NYXOID? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NYXOID and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use NYXOID?

- One spray of NYXOID is given into one nostril.
- Each NYXOID nasal spray contains one single dose of naloxone and cannot be reused. Do not prime or test the device before you give it.
- Call for an ambulance before giving NYXOID.

More instructions can be found in Section 4. How do I use NYXOID? in the full CMI.

5. What should I know while using NYXOID?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using NYXOID.
Driving or using machines	• Do not drive or operate machinery after you have been given NYXOID nasal spray for at least 24 hours (1 day), since the effects of opioids may recur.
Drinking alcohol	• If alcohol has been taken in addition to opioids there may be a delay in the action of naloxone.
Looking after your medicine	• Store below 30°C. Do not freeze

For more information, see Section 5. What should I know while using NYXOID? in the full CMI.

6. Are there any side effects?

Common side effects include dizziness, headache, nausea and vomiting, or high or low blood pressure. You may experience withdrawal symptoms which include:

- restlessness or irritability
- change in mood
- increased skin sensitivity or goosebumps
- vomiting, nausea, stomach or muscle cramps
- sleeping difficulty, anxiety
- sweating, fast heartbeat, high blood pressure, yawning or fever

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

NYXOID® nasal spray

Active ingredient: *Naloxone Hydrochloride Dihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NYXOID. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NYXOID.**

Where to find information in this leaflet:

1. Why am I using NYXOID?
2. What should I know before I use NYXOID?
3. What if I am taking other medicines?
4. How do I use NYXOID?
5. What should I know while using NYXOID?
6. Are there any side effects?
7. Product details

1. Why am I using NYXOID?

NYXOID contains the active ingredient naloxone. Naloxone belongs to a group of medicines that cause temporary reversal of the effects of opioids such as methadone or heroin.

NYXOID is a nasal spray used as part of the emergency treatment of opioid overdose or possible opioid overdose.

Signs of overdose include:

- **breathing problems,**
- **severe sleepiness**
- **not responding to a loud noise or touch.**

If you are at risk of an opioid overdose you should always carry your NYXOID with you. It is designed as an emergency rescue treatment only; you must get emergency medical attention as soon as possible after its use.

2. What should I know before I use NYXOID?

Warnings

Do not use NYXOID if:

- you are allergic to naloxone hydrochloride dihydrate, or any of the ingredients listed at the end of this leaflet.
  Always check the ingredients to make sure you can use this medicine.
- If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor or pharmacist if you:

- Have any other medical conditions, such as
  - heart disease
  - lung disease
  - kidney disease
  - liver disease
- drug addiction (including an addiction to alcohol)
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

If you have received NYXOID close to giving birth or during labour, tell your midwife or doctor. Your baby could suffer from sudden opioid withdrawal syndrome, which could be life-threatening if not treated

If you have not told your doctor about any of the above, tell them before you are given NYXOID.

NYXOID will only be made available after you or your carer have been instructed how to use it

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.
These include but are not limited to:

- pain killers
- cough and cold remedies
- alcohol
- heart or blood pressure medications.

Some medicines may interfere with NYXOID and affect how it works.
If you take opioids to control chronic pain, you may experience pain when you receive NYXOID.

Talk to your doctor before being given NYXOID if you are physically dependent on opioids or if you have received high doses of opioids (for example methadone or heroin). You may get strong withdrawal symptoms if the effects of this medicine occur too quickly.

Talk to your doctor if you use buprenorphine. NYXOID may not fully reverse breathing problems.

These medicines may be affected by NYXOID nasal spray or may affect how well NYXOID nasal spray works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NYXOID.

4. How do I use NYXOID?

How much to use

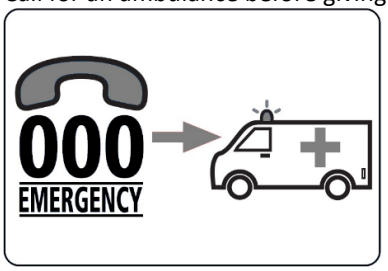
- One spray of NYXOID is given into one nostril.
- Each NYXOID nasal spray contains one single dose of naloxone and cannot be reused.
- The signs and symptoms of an opioid overdose can return after this nasal spray is given. If this happens, or there is no response to treatment, another dose after 2 to 3 minutes using a new nasal spray may be administered.

When to use NYXOID

- **If you or your carer do not understand the instructions on the leaflet, ask your doctor or pharmacist for help.**
- **It is likely that you will be given this medicine by your carer who is trained to do so.**
- **Your carer must call for emergency help immediately before administering the first NYXOID dose.**
- **NYXOID is to be given right away following a suspected overdose and does not take the place of emergency medical care.**
- **Signs of an opioid overdose include breathing problems, severe sleepiness or not being able to respond to a loud noise or touch**

How to give NYXOID

1. Call for an ambulance before giving NYXOID.



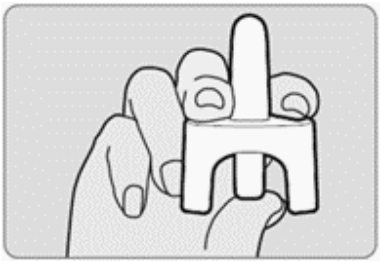
2. Lay the patient on their back. Support the back of the neck and allow the head to tilt back.
3. It's best to check that the nose is clear before giving NYXOID. Should the nose be blocked, a tissue, or piece of material may be used to clear the obstruction before giving NYXOID.



Peel off the back of the blister from the corner to remove the device from the container.



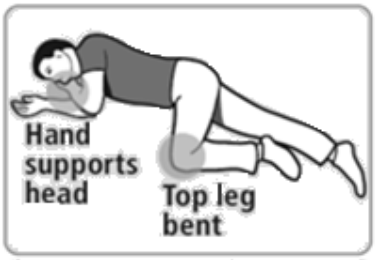
Hold the nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle. **Do not prime or test the device before you give it.**



Gently insert the device nozzle in one nostril of the patient. Press firmly on the plunger until it clicks to give the dose. Remove the nozzle from the nostril after giving the dose. **Each NYXOID nasal spray contains one single dose of naloxone and cannot be reused**.



4. Place the patient into the recovery position on their side with mouth open pointing towards the ground and stay with them until the emergency services arrive. **Watch for an improvement in the patient's breathing level, alertness and response to noise and touch**.



5. If the patient is no better within 2 - 3 minutes, a second dose can be given. Repeat steps 3 and 4 in the other nostril using a new NYXOID nasal spray. However, the patient does not need to be moved from the recovery position to administer additional doses of NYXOID, Once the patient is breathing normally, do not administer further does of NYXOID.
6. Further doses may be given every 2 -3 minutes, if needed, until the emergency services arrive.

In patients who are unconscious and not breathing normally, additional life-saving support can be given if possible, e.g. CPR if you are trained to do so.

If you use too much NYXOID

NYXOID is designed as an emergency rescue treatment only, and you should still get medical attention as soon as possible after its use.

Symptoms of a NYXOID overdose are called 'withdrawal symptoms' which may include:

- restlessness or irritability
- change in mood
- increased skin sensitivity or goosebumps
- vomiting, nausea, stomach or muscle cramps
- sleeping difficulty, anxiety
- sweating, fast heartbeat, high blood pressure, yawning or fever

If you think that you have used too much NYXOID, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre
- (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using NYXOID?

Things you should do

- If you are about to be started on any new medicine, advise your doctor and pharmacist that you have been given NYXOID nasal spray.
- If you are going to have surgery, tell the surgeon or anaesthetist that you have been given NYXOID nasal spray.
  It may affect other medicines used during surgery.
- If you become pregnant while being given NYXOID nasal spray medicine, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you have been given this medicine.
  It may interfere with the results of some tests.

Remind any doctor, dentist or pharmacist you visit that you are using NYXOID.

Things you should not do

- Do not use this medicine after the expiry date which is stated on the carton, blister pack and the label after EXP. The expiry date refers to the last day of that month.

Things to be careful of

- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from a bed or a chair, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.
- Sudden opioid withdrawal syndrome may be life-threatening if not treated properly in children. They should be monitored for at least 24 hours for the signs and symptoms of withdrawal syndrome which include: seizures, crying more than usual and increased reflexes.

Driving or using machines

Do not drive or operate machinery after you have been given NYXOID nasal spray for at least 24 hours (1 day), since the effects of opioids may recur.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Alcohol will not stop NYXOID from working. However, if alcohol has been taken in addition to opioids there may be a delay in the action of naloxone. The nasal spray can be used at any time that it is needed.

Looking after your medicine

- Keep your unused NYXOID devices in the pack
- Keep NYXOID in a place where the temperature stays below 30°C.
- Do not freeze

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

People who are dependent on opioids may suffer from withdrawal symptoms caused by NYXOID suddenly blocking the effect the opioids.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Common side effects

Side effects	What to do
• dizziness • headache • nausea and vomiting • high blood pressure, low blood pressure	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

Side effects	What to do
• sweating • tremor • increased heart rate • nervousness or restlessness • irritability or restlessness • violent behaviour or agitation	**Speak to your doctor as soon as possible.**

Very serious side effects

Side effects	What to do
• shortness of breath • life-threatening irregular heartbeat or heart attack • wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • build up of fluid in the lungs • rash, redness, swelling, severe flaking or peeling, itching or hives on the skin.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What NYXOID contains

Active ingredient (main ingredient)	naloxone hydrochloride dihydrate
Other ingredients (inactive ingredients)	sodium citrate dihydrate sodium chloride hydrochloric acid sodium hydroxide purified water

Do not take this medicine if you are allergic to any of these ingredients.

What NYXOID looks like

NYXOID is provided in a pre-filled nasal spray device and contains naloxone in 0.1 mL of a clear, colourless to pale yellow solution.

NYXOID is packed in a box containing 2 nasal sprays individually sealed in blisters. Each nasal spray contains one single dose of naloxone.

Who distributes NYXOID

Mundipharma Pty Limited

ABN 87 081 322 509

10 Carrington Street

SYDNEY NSW 2000

This leaflet was prepared in December 2020.

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