

NYXOID[®]

Naloxone hydrochloride dihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NYXOID nasal spray. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you being given NYXOID against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NYXOID is used for

This medicine contains the active substance 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.

Ask your doctor or pharmacist if you have any questions about this medicine.

This medicine is available from your pharmacy.

This medicine is not addictive.

Before you are given NYXOID

When you must not be given NYXOID nasal spray

You should not be given NYXOID nasal spray if you have an allergy to:

- any medicine containing naloxone
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include;

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You should not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor or pharmacist.

Before you are given NYXOID nasal spray

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease
- lung disease
- kidney disease
- liver disease
- drug addiction (including an addiction to alcohol)

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket, health food shop, naturopath or herbalist.

These include but are not limited to:

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

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.

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.

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking this medicine.

How NYXOID nasal spray is given

Follow all directions given by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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 much NYXOID nasal spray to give

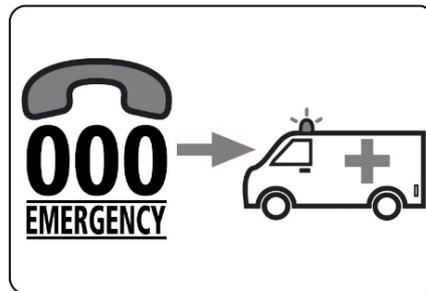
One spray of NYXOID is given into one nostril.

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.

How NYXOID nasal spray is given

1. Call for an ambulance before giving Nyxoid.



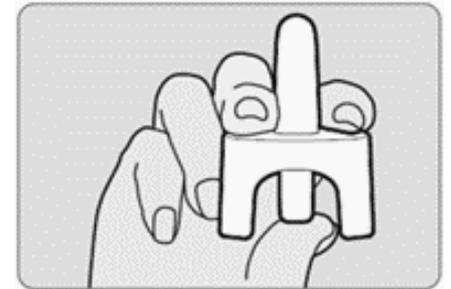
2. Lay the patient on their back. Support the back of the neck and allow the head to tilt back.
3. It's best to check that the nose is clear before giving Nyxoid. Should the nose be blocked, a tissue, or piece of material may be used to clear the obstruction before giving Nyxoid.



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.

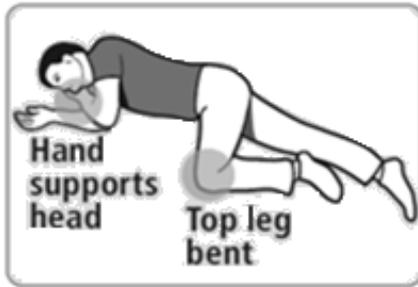


Gently insert the device nozzle in one nostril of the patient. Press firmly on the plunger until it clicks to give the dose. Remove the nozzle from the nostril after giving the dose. Each Nyxoid nasal spray contains one single dose of naloxone and cannot be reused.



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.



- If the patient is no better within 2 - 3 minutes, a second dose can be given. Repeat steps 3-4 in the other nostril using a new Nyxoid nasal spray. However, the patient need not be moved from the recovery position to administer additional doses of Nyxoid. Once the patient is breathing normally, do not administer further doses of Nyxoid.
- 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 take too much (overdose)

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

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much NYXOID nasal spray. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

While you are being given NYXOID nasal spray

Things you must 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.

Tell any other doctors, dentists, who treat you 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.

Things you must not do

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.

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.

Side effects

Tell your doctor, or nurse as soon as possible if you do not feel well after being given NYXOID nasal spray.

This medicine helps most people reverse a life threatening opioid overdose, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or nurse to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness
- headache
- nausea and vomiting
- high blood pressure, low blood pressure

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- sweating
- tremor
- increased heart rate
- nervousness or restlessness
- irritability or restlessness
- violent behaviour or agitation

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.

The above list includes very serious side effects. You may need urgent medical attention or further hospitalisation.

Tell your doctor or healthcare professional if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given NYXOID

Storage

Keep your unused NYXOID devices in the pack.

Keep NYXOID in a cool dry place where the temperature stays below 30°C.

Do not store NYXOID or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

This medicine 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.

Ingredients

NYXOID contains 1.8 mg of naloxone (as naloxone hydrochloride dihydrate) as the active ingredient.

The other ingredients are:

- sodium citrate dihydrate
- sodium chloride
- hydrochloric acid
- sodium hydroxide
- purified water

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dye.

Sponsor

NYXOID is sponsored in Australia by:

Mundipharma Pty Limited
ABN 87 081 322 509
88 Phillip Street

SYDNEY NSW 2000

This leaflet was prepared in September 2018

NYXOID nasal spray: AUST R 309381

® NYXOID is a trade mark of MUNDIPHARMA

RA-0205