Naloxone 1.26 mg nasal spray, solution in single-dose container
naloxone

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Package leaflet: Information for the user

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Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Naloxone 1.26 mg nasal spray is and what it is used for
2. What you need to know before you receive Naloxone 1.26 nasal spray
3. How to give Naloxone 1.26 mg nasal spray
4. Possible side effects
5. How to store Naloxone 1.26 mg nasal spray
6. Contents of the pack and other information

1. What Naloxone 1.26 mg nasal spray is and what it is used for

Naloxone 1.26 mg nasal spray contains the active ingredient naloxone which is an opioid antidote. This medicine is used to reverse the effect of known or suspected opioid overdose in adults (e.g. morphine, heroin, methadone, fentanyl, oxycodone or buprenorphine).

Naloxone 1.26 mg nasal spray is a nasal spray used for the emergency treatment of opioid overdose or possible opioid overdose in adults. 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 Naloxone 1.26 mg nasal spray with you. Naloxone 1.26 mg nasal spray works for a short time only to reverse the effects of opioids while you wait for emergency medical attention. It is not a substitute for emergency medical care.
Always tell your friends and family that you carry Naloxone 1.26 mg nasal spray with you.

2. What you need to know before you receive Naloxone 1.26 mg nasal spray

Do not use Naloxone 1.26 mg nasal spray:
– if you are allergic to naloxone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
This medicine is used for emergency treatment in situations of acute opioid overdose and must be given by someone other than yourself.

Naloxone 1.26 mg nasal spray is to be given right away and does not take the place of standard emergency medical care. Call for emergency medical help right away, even if the person wakes up. CALL 999 or 112.

– **One nasal spray of Naloxone 1.26 mg nasal spray contains only one dose of naloxone.** It is important that the nasal spray is not primed or tested prior to use, as this will empty the nasal spray and you will not receive the medicine you need. Use a second Naloxone 1.26 mg nasal spray nasal spray, if additional doses are required. Additional doses can be given after 2 to 3 minutes after the initial dose(s) (see section 3).
– **Symptoms of acute withdrawal syndrome:** It is possible that Naloxone 1.26 mg nasal spray can lead to a too rapid reversal of the opioid effect which may cause an acute withdrawal syndrome in persons who are physically dependent on opioids. Symptoms of acute withdrawal syndrome can be fast heart rate, high blood pressure, body aches and stomach cramps, diarrhoea, nausea, vomiting, sweating, fever, goose bumps, shivering or trembling, changes in behaviour including violent behaviour, nervousness, anxiety, excitement, restlessness or irritability, unpleasant or uncomfortable mood, increased skin sensitivity, difficulty in sleeping. If you are taking opioids for the relief of chronic pain, you may also experience increased pain when you receive Naloxone 1.26 mg nasal spray.
– **The duration of effect of some opioids may exceed that of Naloxone 1.26 mg nasal spray.** Even if an initial response is observed, it is important that patients are kept under observation, as the signs and symptoms of opioid overdose may come back. In this case additional doses of Naloxone 1.26 mg nasal spray can be administered (see section 3).
– **If you use buprenorphine**, be aware that Naloxone 1.26 mg nasal spray may not fully reverse breathing problems and an additional dose may be required.
– **Tell your doctor if you have damage to the inside of your nose** as this could affect how Naloxone 1.26 mg nasal spray works.

Children and adolescents
Do not use this medicine in children and adolescents.

Other medicines and Naloxone 1.26 mg nasal spray
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you are using or have used high doses of opioids or long acting opioids, tell your doctor.

Naloxone 1.26 mg nasal spray with alcohol
The onset of effect of this medicine may be slower in patients with intoxication caused by opioids and alcohol.

Pregnancy and breast-feeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before obtaining this medicine. If you are given Naloxone 1.26 mg nasal spray while you are pregnant or breast-feeding, your baby should be closely monitored.

Driving and using machines
As the effect of opioids may return, do not drive or use machines, or perform physically or mentally challenging tasks for at least 24 hours after treatment with Naloxone 1.26 mg nasal spray.

Naloxone 1.26 mg nasal spray contains benzalkonium chloride
This medicine contains 0.02 mg benzalkonium chloride in each nasal spray, which is equivalent to 0.2 mg/ml. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How to give Naloxone 1.26 mg nasal spray

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults:
One spray (1.26 mg naloxone) given intranasally (into the nose).
First aid should be given until healthcare professionals (HCP) are on the site. Place the patient into recovery position. If no significant clinical effect is achieved or the condition worsens following initial treatment, one additional dose may be administered after 2-3 minutes.

If two doses of 1.26 mg naloxone do not result in a significant improvement in symptoms, it should be considered that the symptoms may be caused completely or partially by other factors or substances than opioids.

Instructions for Use

1. **Check for symptoms and response.**
   – **Check for a response, to see if the person is conscious.** You can shout their name, gently shake their shoulders, talk loudly into their ears, rub their breastbone (sternum), pinch their ear or the bed of their fingernail.
   – **Check airways and breathing.** Clear the mouth and nose of any blockages. For 10 seconds check for breathing – is the chest moving? Can you hear breathing sounds? Can you feel breath on the cheek?
   – **Check for signs of overdose**, such as: no response to touch or sounds, slow uneven breathing or no breathing, snoring, gasping or gulping, blue or purple fingernails or lips.
   – **If an overdose is suspected Naloxone 1.26 mg nasal spray should be given.**
2. Call emergency medical services. CALL national rescue number 999 or 112.



3. Place the patient on his/her back. Ensure free airways. It is recommended to inspect and clear the nasal airway before giving the nasal spray.



4. Open the blister or inner packaging by first removing the rubber band, then pressing at the centre of both flat sides of the plastic pebble to open.



Do not prime or test the nasal spray prior to use. One nasal spray of Naloxone 1.26 mg nasal spray contains only one dose of naloxone.

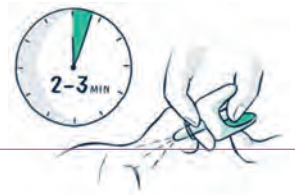
5. Support the back of the neck to allow the head to tilt back. Insert the spray nozzle into one nostril. Press firmly on the plunger until it clicks to give the dose, then remove the nasal spray from the nostril.



6. Place the patient into recovery position. Stay with the patient until the emergency services arrive. Watch for an improvement in the patient's breathing level, alertness and response to noise and touch.



7. If there is no improvement, a second dose should be given after 2-3 minutes in the other nostril.



For instruction video, see QR code and URL at the end of the package leaflet.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

It can be difficult to know if a side effect is due to use of Naloxone 1.26 mg nasal spray as it is always given after use of opioids.

Possible side effects include

Very common (may affect more than 1 in 10 people)
- feeling sick

Common (may affect up to 1 in 10 people):
- dizziness, headache
- fast heart beat
- increased or lowered blood pressure (you may experience headache or a sensation of fainting)
- being sick (vomiting)

Uncommon (may affect up to 1 in 100 people):
- tremor, sweating
- irregular heart beat, slow heart beat
- diarrhoea, dry mouth
- rapid breathing
- withdrawal symptoms such as restlessness or irritability, increase of skin sensitivity, feeling sick, vomiting, stomach cramps, muscle cramps, unpleasant or uncomfortable mood, difficulty in sleeping, anxiety, sweating, goose bumps, fast heartbeat rate, high blood pressure, yawning and fever

Very rare (may affect up to 1 in 10,000 people):
- allergic reactions such as swelling of the face, mouth, lips or throat, allergic shock
- life-threatening irregular heartbeat, heart attack
- build-up of fluid in the lungs
- skin problems such as itching, rash, redness, swelling, severe flaking or peeling of the skin

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Naloxone 1.26 mg nasal spray

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the single-dose container, blister pack/plastic cover and carton after EXP: The expiry date refers to the last day of that month.

Do not freeze. Keep the single-dose containers in the plastic cover in order to protect from light. Keep the blister pack in the carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Naloxone 1.26 mg nasal spray contains

- The active substance is naloxone. Each nasal spray container delivers 1.26 mg of naloxone (as hydrochloride dihydrate)
- The other excipients are povidone, glycerol, disodium edetate, benzalkonium chloride, citric acid monohydrate, sodium citrate, sodium hydroxide (for pH-adjustment), hydrochloric acid (for pH-adjustment), water for injections.

What Naloxone 1.26 mg nasal spray looks like and contents of the pack

Naloxone 1.26 mg nasal spray is a clear, colourless solution packed in a glass vial with a rubber stopper inside a spray device comprised of polypropylene and stainless steel. No further device assembly is required.

Pack sizes:
Carton with 1 plastic cover contains 2 single-dose containers of 0.1 ml nasal spray.
Carton with 10 plastic covers each containing 2 single-dose containers of 0.1 ml nasal spray.
Carton with 6 blister packs each containing 1 single-dose container of 0.1 ml nasal spray.

Marketing Authorisation Holder
Navamedic ASA
Henrik Ibsens gate 100
NO-0255 OSLO
NORWAY

Manufacturer
Pharma Production AS
Karihaugveien 22
NO-1086 OSLO
NORWAY

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland under the following names:

Member State	Name
Belgium, Denmark, Estonia, Finland, France, Germany, Ireland, Italy, Netherlands, Norway	Ventizolve
Sweden	Respinal
United Kingdom (Northern Ireland)	Naloxone 1.26 mg

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Accord-UK Ltd
Tel: +44 (0)1271 385257

This leaflet was last revised in August 2026.

Latest approved information (Package Leaflet, Quick Start Guide and Video for this medicine is available by scanning this QR code (also included on the outer carton with a smartphone/device. The same information is also available on the following URL: www.naloxone.uk

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