Package leaflet: Information for the user

{(Invented) name} 1.8 mg Nasal Spray, solution in single dose container.
{(Invented) name} 3.6 mg Nasal Spray, solution in single dose container.
naloxone

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 or nurse.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet (See section 4).

What is in this leaflet

1. What {(Invented) name} is and what it is used for

This medicine contains the active substance naloxone. {(Invented) name} temporarily reverses the effects of opioids such as heroin, methadone, fentanyl, oxycodone, buprenorphine and morphine.

{(Invented) name} is a nasal spray used for the emergency treatment of opioid overdose or possible opioid overdose in adults.

Signs and symptoms of an opioid overdose includes:
- breathing problems
- extreme sleepiness
- extremely small pupils in the eye
- not responding to a loud noise or touch

If you are at risk of an opioid overdose you should always carry {(Invented) name} with you.
{(Invented) name} 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. {(Invented) name} is intended for use by appropriately trained individuals.

Always tell your friends and family that you carry {(Invented) name} with you.

2. What you need to know before you are given {(Invented) name}

You should not be given {(Invented) name}
- if you are allergic to naloxone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

{(Invented) name} will be supplied to you only after you or the person who will be giving the medicine to you have been taught how to recognise the symptoms of an opioid overdose, and how to correctly use the medicine.

It is to be given right away and does not replace emergency medical care.
Emergency services should be called if an opioid overdose is suspected.
The signs and symptoms of an opioid overdose can return after this nasal spray is given. If this happens, further doses maybe given after 2 to 3 minutes using a new nasal spray. The patient should be monitored closely until emergency help has arrived after being given this medicine.

Opioid withdrawal symptoms
If you are physically dependent on opioids, treatment with this medication may result in the sudden appearance of **opioid withdrawal symptoms**. This may include body aches, diarrhoea, fast heartbeat, fever, runny nose, sneezing, goose bumps, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

Elderly
If you are an elderly patient with an existing heart condition, or if you are receiving other drugs which may affect your heart, this medication should be used with caution.

Children and adolescents
The use of {(Invented) name} has not been studied in children under 18 years of age. {(Invented) name} is indicated for use in adults only.

Other medicines and {(Invented) name}
Tell your doctor if you are taking or have recently taken any other medicines.

- If you are taking painkilling medication like buprenorphine, the painkilling effect may even become stronger while you are treated with {(Invented) name}. However, the reversal of unwanted effects, like respiratory depression caused by buprenorphine may be limited.

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 receiving a supply of this medicine.

Tell your midwife or doctor if you have **received** {(Invented) name} close to or during **labour.**
Your baby could suffer from **sudden opioid withdrawal syndrome,** which could be life-threatening if not treated.
Watch out for the following symptoms in your baby during the first **24 hours** after the baby is born:
- seizures (fits)
- crying more than usual
- increased reflexes.

If you are given {(Invented) name} while you are pregnant or breast-feeding, your baby should be closely monitored.

Driving and using machines
After receiving {(Invented) name} for the reversal of the effects of opioids you must not take part in road traffic, operate machinery or engage in any other physically or mentally demanding activity for at least 24 hours since the effects of opioids may possibly recur.

{(Invented) name} **contains benzalkonium chloride**
This medicine contains 0.01 mg benzalkonium chloride in each spray.

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How {(invented) name} is to be given

{(Invented) name} is for nasal use.

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

Training will be provided on how to use {(Invented) name} before it is supplied to you.

This medicine is not a substitute for emergency medical care. **Instructions for giving {(Invented) name} nasal spray is found at the end of this leaflet.**

After {(Invented) name} has been given the effects are usually seen after two to three minutes.

The recommended doses are:

Adults:	A single spray into one nostril. If you do not respond to the first dose after two to three minutes, additional doses may be given. If you respond to the first dose, but subsequently become unconscious or stop breathing again, additional doses may be given.

{(Invented) name} is available in two strengths; 1.8 mg and 3.6 mg. The doctor will decide the dose for you.

Use in elderly
Older patients may have reduced liver, kidney and heart function, and may suffer from other diseases or be in receipt of other medications. These factors will be taken into account by your doctor when deciding your dose, since they may result in you being exposed to higher doses of naloxone.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

It may be difficult to know what side effects {(Invented) name} has, because it is always given after other drugs have also been used.

Below are the adverse events associated with naloxone when given as an injection. The following side effects may be serious. If any of the following side effects occur, consult a doctor immediately:

Common (may affect up to 1 in 10 people):
- Fast heart beat

Uncommon (may affect up to 1 in 100 people):
- Changes in the way your heart beats, slow heart rate

Rare (may affect up to 1 in 1,000 people):
- Seizures

Very rare (may affect up to 1 in 10,000 people):

- Allergic reactions, (nettle type rash, inflammation of the nasal cavity, difficulty breathing, angioedema (with symptoms such as swollen face, tongue or pharynx, difficulty to swallow and breath), allergic shock
- Fibrillation (excessive and irregular contractions of the heart chambers), cardiac arrest
- Fluid on the lungs (pulmonary oedema, with symptoms such as fast heart beat and sweating)

Side effects seen with naloxone when given as a nasal spray

Not known (cannot be established from the available data):

- Erythema (redness of skin) of nasal mucosa
- Oedema (swelling) of nasal mucosa
- Nasal Pain
- Headache

Other side effects associated with naloxone when given as an injection:

Very common (may affect more than 1 in 10 people):

- Nausea

Common (may affect up to 1 in 10 people):

- Dizziness
- Headache
- Increased or decreased blood pressure
- Vomiting
- If a too large dose is given after an operation, you may become excited and feel pain.

Uncommon (may affect up to 1 in 100 people):

- Involuntary trembling or quivering (tremor)
- Sweating
- Diarrhoea
- Dry mouth
- Over breathing (hyperventilation)
- Irritation of vessel wall has been reported after naloxone has been given intravenously (through a vein)
- Local irritation and inflammation have been reported after naloxone has been given intramuscularly (in a muscle).

Rare (may affect up to 1 in 1,000 people):

- Tension

Very rare (may affect up to 1 in 10,000 people):

- Discoloration and lesions of the skin (erythema multiforme)

Not known (cannot be established from the available data):

- Runny nose, sneezing
- Yawning
- Fever
- Agitation when administered in excessive doses to patients after operations
- Reversal of effects of pain relieving medication when administered in excessive doses to patients after operations
- Weakness
- Shivering

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below).

By reporting side effects you can help provide more information on the safety of this medicine.

"To be completed nationally"

5. How to store {(invented) name}

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 label and the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not freeze.

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

6. Contents of the pack and other information

What {(Invented) name} **contains**

- The active substance is naloxone.
- Each 0.1 mL dose contains naloxone hydrochloride dihydrate equivalent to 1.8 mg or 3.6 mg naloxone.
- The other ingredients are benzalkonium chloride (see section 2), disodium edetate, sodium chloride, hydrochloric acid (for pH adjustment) and water.

What {(Invented) name} **looks like and contents of the pack**

{(Invented) name} is a clear or colourless or slightly yellow solution in a nasal spray device.
Pack sizes: 2 blisters each containing a {(Invented) name} spray device.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

Adapt Pharma Operations Ltd,
6th Floor,
6 Earlsfort Terrace,
Dublin 2,
Ireland

Manufacturer:

Manufacturing Packaging Farmaca B.V.
Neptunus 12
8448 CN Heerenveen
The Netherlands

Manufacturing Packaging Farmaca B.V.

Appelhof 13
8465 RX Oudehaske
The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden, France, Italy Estonia	*Naloxone Adapt 1.8 mg/3.6 mg Nasal Spray, solution in single dose container*
UK, Ireland	*Narcan 1.8 mg/3.6 mg Nasal Spray, solution in single dose container*
Germany	*Narcan 1.8 mg/3.6 mg Nasenspray, Lösung im Einzeldosisbehältnis*

This leaflet was last revised in 2019-10-17

Other sources of information

This package leaflet is available in formats that are suitable for the blind or partially sighted. Such formats are available on request.

Step-by-step guide to using {(Invented) name}

This medicine is not a substitute for emergency medical care.

Do not remove the nasal spray device from its blister until ready to use. Each spray device is sealed in a blister to keep it clean and safe. If you carry a spray device without a blister, or in an open blister, it may not work properly when you need it.

Each spray device contains just one dose of the medicine.

Do not test or prime the spray device or you will lose the dose.

The spray device is for single use only.

The {(Invented) name} spray device has 3 parts:

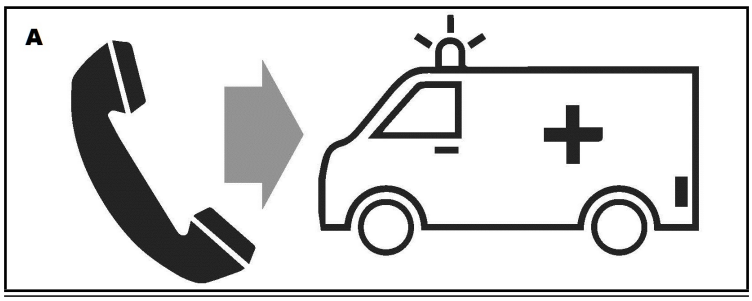
The nozzle
The part you put in the patient's nostril.
The spray comes out of a tiny hole in the top.

The finger-grip
Hold this when you use the spray.

The plunger
Press this to spray the whole dose into the nostril in one go.
This only works once - don't press the plunger until you have put the nozzle into the nostril or you will lose the dose.

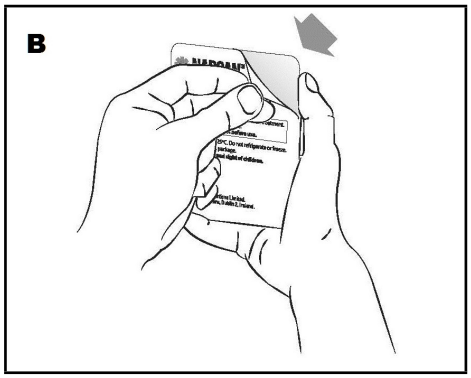
1. **Check for symptoms and response**.
   - **Check for a response, to see if the person is conscious.** You can shout their name, gently shake their shoulders, talk loudly into their ears, rub their breastbone (sternum), pinch their ear or the bed of their fingernail.
   - **Check airways and breathing.** 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 {(Invented) name} should be given.**

2. **Call for an ambulance (Picture A). {(Invented) name}** is not a substitute for emergency medical care.

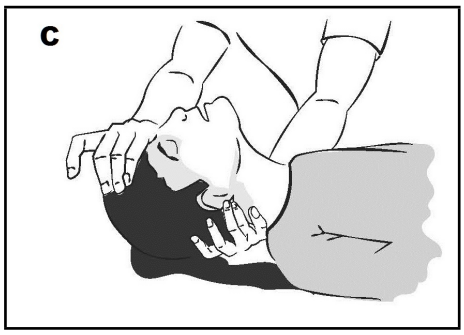


How to use {(Invented) name}

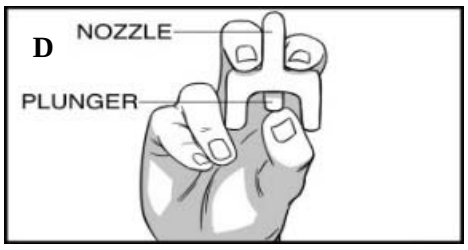
3. Remove the spray device from the blister packaging just before you need to use it (Picture B).



4. Place the patient on their back to receive a dose of the medicine. Provide support to the back of the neck to allow the head to tilt back as per Picture C.

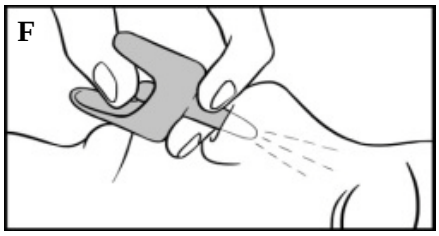


5. Hold the spray device with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle as shown in Picture D. Don't press the plunger yet.



6. Gently insert the tip of the nozzle into either nostril until your fingers on either side of the nozzle are against the bottom of the nose as shown in Picture E.

7. Press the plunger firmly with your thumb to administer the dose of medicine (Picture F).

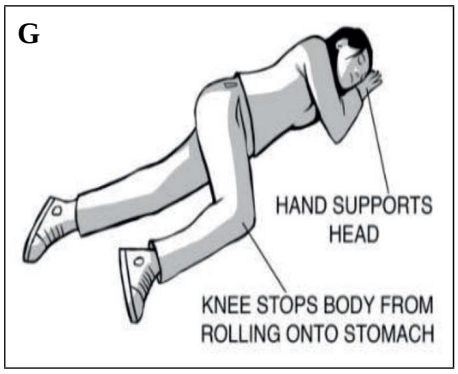


8. Remove the spray device from the nostril after giving the dose.

9. If the person does not respond (by waking, to voice or touch, or breathing normally) within 2-3 minutes, a second dose can be given. Be aware – even if the patient wakes up, he/she may become unconscious again, and stop breathing. If this happens, a second dose can be given immediately. Give the medicine in the other nostril using a new {(Invented) name} nasal spray.
   In patients who are not breathing normally give basic life support by giving the patient 30 chest compressions and 2 rescue breaths if possible.

   If the patient does not respond to two doses, further doses may be given (if available).

   If the patient is breathing normally, move the patient on to their side (recovery position, Picture G). Stay with the patient and continue to watch for an improvement until the emergency services arrive who will give further treatment.



10. Put the used spray device back in its box and dispose of in accordance with local requirements and in a location that is protected from children.