Package leaflet: Information for the user

Naloxon actrevo 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.
Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 Naloxon actrevo is and what it is used for

This medicine contains the active substance naloxone, an antidote against opioids. Naloxone temporarily reverses the effects of opioids such as heroin, methadone, fentanyl, oxycodone, buprenorphine and morphine.

Naloxon actrevo is a nasal spray used for the emergency treatment of opioid overdose or possible opioid overdose in adults and adolescents aged 14 years and over. 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 Naloxon actrevo with you.
Naloxon actrevo 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. Naloxon actrevo is intended for use by appropriately trained individuals.
Always tell your friends and family that you carry Naloxon actrevo with you.

2. What you need to know before you receive Naloxon actrevo

Do not use Naloxon actrevo:

If you are allergic to naloxone or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions

- This medicine is used for emergency treatment opioid overdose and must be given to you by someone else.
- It is to be given right away and does not take the place of emergency medical care.
- **Call an ambulance immediately, even if the person comes to consciousness. Call [To be completed nationally].**

- **One nasal spray of Naloxon actrevo 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.

- **A second dose of Naloxon actrevo may be needed.** The signs and symptoms of an opioid overdose can return after this nasal spray is given. If this happens, further doses may be 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 (see section 3).

- **Conditions to look out for**
- Naloxon actrevo may cause a too rapid reversal of the opioid effect and you may get severe withdrawal symptoms if you are physically dependent on opioids or if you have received high doses of opioids. See section 4 'Withdrawal symptoms'.
- If you take opioids to control pain, the pain may also increase when you receive Naloxon actrevo.
- **If you use buprenorphine,** Naloxon actrevo may not fully reverse breathing problems.

- **Tell your doctor if you have damage to the inside of your nose** as this could affect how Naloxon actrevo works.

Children and adolescents

Naloxon actrevo is not for use in children or adolescents under 14 years.

Other medicines and Naloxon actrevo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, 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.
If you are given Naloxon actrevo while you are pregnant or breast-feeding, your baby should be closely monitored.

Receiving Naloxon actrevo close to giving birth

Tell your midwife or doctor if you have **received Naloxon actrevo** 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.

Driving and using machines

After taking this medicine, you must not drive, operate machinery or engage in any other physically or mentally demanding activity for at least 24 hours, since the effects of opioids may recur.

Naloxon actrevo contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially sodium free.

Naloxon actrevo contains benzalkonium chloride
This medicine contains 0.012 mg benzalkonium chloride in each single-dose container which is equivalent to 0.12 mg/ml.
Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How Naloxon actrevo is to be given

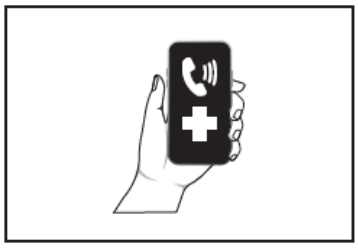
Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.
Training will be provided on how to use Naloxon actrevo before it is supplied to you.

If suspected opioid overdose in adults and adolescents aged 14 years and over, call ambulance and give one dose in one nostril. If the patient gets worse or is no better within 2-3 minutes, a second dose can be given in the other nostril.
Below is a step by step guide.

Instructions for giving Naloxon actrevo nasal spray

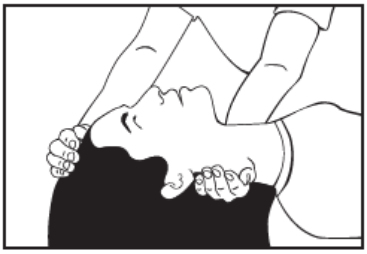
1. **Check for symptoms and response**
   - **Check for a response, to see if the person is conscious**. You can shout their name, gently shake their shoulders, talk loudly into their ears, rub their breastbone (sternum), pinch their ear or the bed of their fingernail.
   - **Check airways and breathing**.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

2. **Call for an ambulance. Call [To be completed nationally].** Naloxon actrevo is not a substitute for emergency medical care.

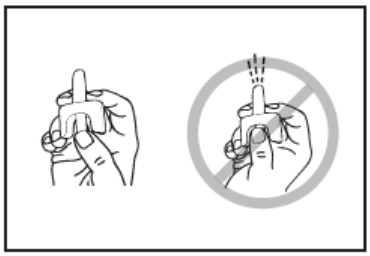


3. **Peel off** the back of the blister from the corner to remove the nasal spray from the container. Place the nasal spray within easy reach.

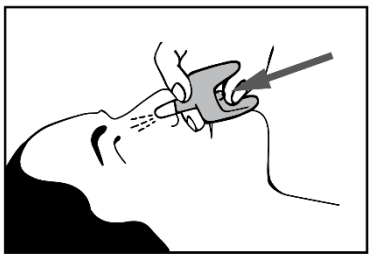
4. Lay the patient on their back. Support the back of the neck and allow the head to tilt back. Clear away anything blocking their nose.



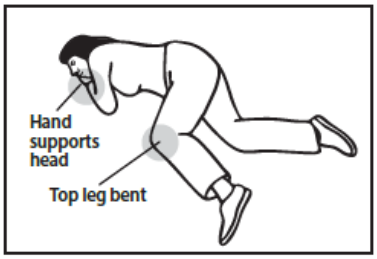
5. Hold the nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle. **Do not prime or test the Naloxon actrevo nasal spray before use** as it contains only one dose of naloxone and cannot be reused.



6. Gently insert the device nozzle in **one nostril**. **Press firmly** on the plunger **until it clicks** to give the dose. Remove the nasal spray nozzle from the nostril after giving the dose.



7. Place the patient into the **recovery position** on their side with mouth open pointing towards the ground and 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.



8. If the patient is **no better within 2-3 minutes**, a **second dose can be given**. Be aware – even if they wake up, they may become unconscious again, and stop breathing. If this happens, a second dose can be given immediately. Give Naloxon actrevo in the other nostril using a new Naloxon actrevo nasal spray. This can be done **while the patient is in the recovery position**.

9. If the patient does not respond to two doses, further doses may be given (if available). Stay with the patient and continue to watch for an improvement until the emergency services arrive who will give further treatment.

In patients who are unconscious and not breathing normally additional life-saving support should be given if possible.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everyone gets them. The side effects below may happen with this medicine.

Withdrawal symptoms
Naloxon actrevo can cause withdrawal symptoms if you are dependent on opioid drugs. Uncommon: may affect up to 1 in 100 people
Symptoms can be: restlessness, irritability, increased skin sensitivity, nausea, vomiting, stomach cramps, muscle spasms, unpleasant or uncomfortable mood, difficulty in sleeping, anxiety, excessive sweating, goose bumps, fast heart rate, increased blood pressure, yawning, fever, behavioural changes such as violent behaviour, nervousness and excitement.

Other side effects

Very common: may affect more than 1 in 10 people
- Feeling sick (Nausea)

Common: may affect up to 1 in 10 people
- Dizziness, headache
- Fast heart rate
- High blood pressure, low blood pressure
- Being sick (vomiting)

Uncommon: may affect up to 1 in 100 people
- Tremor
- Slow heart rate
- Sweating
- Irregular heart beat
- Diarrhoea
- Dry mouth
- Rapid breathing

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Naloxon actrevo

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

Do not freeze. If accidentally frozen, the nasal spray will not function. Allow the nasal spray to thaw for at least one hour; do not use if the contents are still frozen or not completely thawed. Freezing does not affect the shelf life of the product.

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

6. Contents of the pack and other information

What Naloxon actrevo contains

- The active substance is naloxone. Each nasal spray contains 3.6 mg of naloxone (as hydrochloride dihydrate).
- The other ingredients are: Benzalkonium chloride solution 50%, disodium edetate, sodium chloride, hydrochloric acid (for pH-adjustment), purified water. See section 2 ‘Naloxon actrevo contains sodium’ and ‘Naloxon actrevo contains benzalkonium chloride’.

What Naloxon actrevo looks like and contents of the pack

This medicine contains naloxone in 0.1 ml of a clear, colourless to yellowish solution in a pre-filled nasal spray, solution in single dose container (nasal spray, solution).
Naloxon actrevo is packed in a carton containing 2 nasal sprays individually sealed in blisters. Each nasal spray contains one single dose of naloxone.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:
[To be completed nationally]

This leaflet was last revised in 4 Mar 2026 <{MM/YYYY}>
[To be completed nationally]