

Client's Guide to Prenoxad Injection

When you or someone you represent has been prescribed Prenoxad Injection (naloxone hydrochloride 1mg/1ml solution for injection)

Introduction

The purpose of this booklet is to provide you with important information about Prenoxad Injection and how to use it.

- 1. What is Prenoxad Injection and what is it used for?
- 2. How do I get Prenoxad Injection?
- 3. When should I use Prenoxad Injection?
- 4. How do I use Prenoxad Injection?
- 5. How do I assemble and inject Prenoxad Injection?
- 6. How do I dispose of Prenoxad Injection?
- 7. How do I put someone into the recovery position?
- 8. How do I give chest compressions and rescue breaths (CPR) to an adult?
- 9. What will happen immediately after injecting Prenoxad Injection and what should I do?
- 10. What are the risks of taking Prenoxad Injection?
- 11. Who can I contact for further information?

This document summarises important information from the Prenoxad Injection Patient Information Leaflet (provided with Prenoxad Injection), but is not intended to replace it.

What is Prenoxad Injection and what is it used for?

Prenoxad Injection contains the medicine naloxone hydrochloride. Naloxone hydrochloride reverses the action of opioid drugs such as morphine, diamorphine (heroin), methadone, codeine and dihydrocodeine and dextropropoxyphene. Prenoxad Injection will also partially reverse the effects of buprenorphine.

If someone has accidentally overdosed, and an opioid drug such as those mentioned above is involved, Prenoxad Injection can be used to reverse the action of the drug. Prenoxad Injection is designed to be used as an emergency rescue treatment so you should still get medical attention as soon as possible by calling for an ambulance. This is because Prenoxad Injection will wear off after a short time and there is a danger of the casualty going back into an overdose.

How do I get Prenoxad Injection?

Prenoxad Injection is prescribed to people who may be at risk of future opioid or opioid-related overdose. It can also be supplied to the friends, family or other representative of someone identified as being at risk, but only with the written consent from the person for whom it is to be supplied.

Before supplying Prenoxad Injection, the prescriber will need to be sure that you or your representative understands when and how to use Prenoxad Injection. This will involve you being trained on using Prenoxad Injection. A representative may also be trained on using Prenoxad Injection, however, they can only receive a supply of Prenoxad Injection if you give written consent. The training might be carried out by the prescriber or by someone who works in drug and alcohol treatment services.

You should always carry your Prenoxad Injection with you and tell your representative and other family or friends where they can find it in an emergency.

When should I use Prenoxad Injection?

Prenoxad Injection should only be used in an emergency situation where it is known or suspected that an overdose has occurred and opioid drugs may be involved.

The signs and symptoms of an opioid overdose are:

- Pinpoint pupils (indicates opioid use)
- Pale skin colour
- Bluish tinge to lips, tip of nose, eye bags, fingertips or nails
- No response to noise (where the helper 'shouts' at the casualty and gets no response)
- No response to touch (shoulder shake)
- Loss of consciousness i.e. the suspected overdose casualty cannot be woken
- Breathing problems
 - Slow/shallow or infrequent breaths
 - Snoring/rasping sounds
 - Not breathing at all

When someone has overdosed they can look and sound like they are just asleep. Always check when you hear snoring that the person is actually asleep and not in an overdose situation. Snoring/rasping can be an indication of breathing difficulties.

The time gap between a person taking (e.g. injecting) drugs and slipping into an overdose and can vary from a few minutes to several hours.

How do I use Prenoxad Injection?

When accidental opioid or opioid-related overdoses occur, there is a simple process to follow.

Approach the suspected casualty with caution and care, watching out for anything that might be dangerous to you or the casualty. These dangers may vary depending on where the suspected casualty has been found i.e. outside (there may be broken glass on the ground, traffic nearby etc.) or indoors in a home environment (close to a fire/heat source, cables, wires etc.).

It may also be the case that other potential dangers could be present, such as injecting equipment (needles/syringes etc). If you see a needle or syringe near the casualty and it may pose a threat to you or the casualty if you need to move them (for example) into the recovery position, then you may need to move the injecting equipment safely.

MAKE SURE IT IS SAFE FOR YOU TO APPROACH THE CASUALTY BEFORE YOU DO SO.

You should begin by speaking to the casualty from a safe distance, saying "open your eyes" or "wake up". If there is no response to this, start to use a louder voice (shouting), making the same statements to the casualty. As you continue to approach, keep looking out for dangers and continue to use your voice like this.

Once you are next to the casualty try to get a response from them by shaking their shoulders and shouting "open your eyes" or "wake up" into each ear. If they don't wake or respond, you may need to move them from a sitting position, or if they are lying on a sofa/in a bed onto the floor. Once the casualty is lying on a flat surface, make sure you open their airway by gently tilting their head back and opening their mouth. Look, listen and feel for signs of breathing for no more than 10 seconds.

What you do next depends on whether the person is breathing or not. If the casualty is not breathing normally (i.e. you have not detected 1 or 2 breaths/ breathing in the casualty during the 10 second assessment):

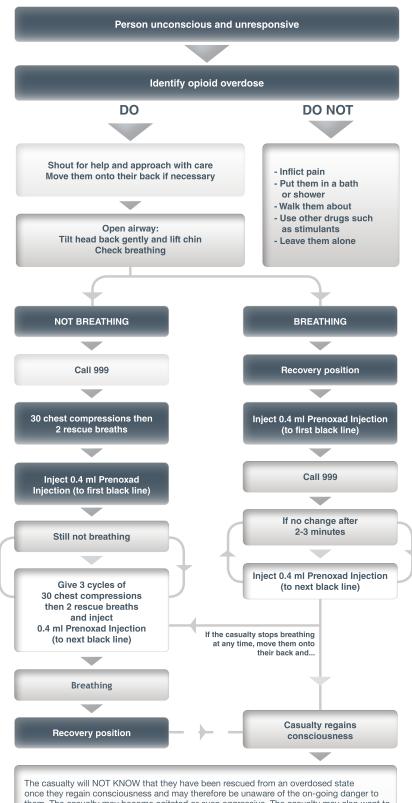
- 1. Call 999 immediately and ask for an ambulance, explaining that the casualty is UNCONSCIOUS AND NOT BREATHING NORMALLY
- 2. Give basic life support by giving 30 chest compressions and attempting 2 rescue breaths if possible (see instructions on page 13)
- 3. Give 0.4 ml Prenoxad Injection:
 - Open and assemble Prenoxad Injection (see diagram on page 9)
 - Hold the syringe like a pen
 - Inject the casualty with Prenoxad Injection. The needle should be inserted into the casualty's outer thigh or upper arm muscle at a right angle to the surface of the skin (see diagram on page 10), straight through clothing if required
 - Push the plunger to the first black line
 - Withdraw the needle from the casualty's thigh or upper arm muscle and put the syringe (with the needle still attached) back into the 'cradle' in the Prenoxad Injection case. It will fit into the cradle even with the needle attained.
 - DO NOT ATTEMPT TO REMOVE OR RE-SHEATH THE NEEDLE
- 4. If the casualty is still not breathing normally, give 3 more sets of 30 chest compressions and 2 rescue breaths followed by one dose of 0.4 ml Prenoxad Injection. Inject Prenoxad Injection following the same process and using the same needle as before. Repeat this as many times as necessary until:
 - The casualty starts breathing normally
 - The ambulance arrives
- 5. If the casualty begins to breathe normally, move them to the recovery position, lying on their side, mouth open and pointing towards the ground (see diagram on page 12). Stay with them and continue to monitor their breathing

If medical assistance has not arrived after you have used up the contents of one Prenoxad Injection syringe and you have a second Prenoxad Injection syringe available, even if it has not been prescribed to you, it may be used in the same way as the first. Using the second Prenoxad Injection in this way does not risk the person's safety.

If the casualty is breathing normally (i.e. you have detected 1 or 2 breaths/ breathing in the casualty during the 10 second assessment) but is unconscious or not rousable (i.e. can't be woken up):

- 1. Move the casualty into the recovery position, lying on their side, mouth open and pointing towards the ground (see diagram on page 12)
- 2. Give 0.4 ml Prenoxad Injection:
 - Open and assemble Prenoxad Injection (see diagram on page 9)
 - Hold the syringe like a pen
 - Inject the casualty with Prenoxad Injection. The needle should be inserted into the casualty's outer thigh or upper arm muscle at a right angle to the surface of the skin (see diagram on page 10), straight through clothing if required
 - Push the plunger to the first black line
 - Withdraw the needle from the casualty's thigh or upper arm muscle and put the syringe (with the needle still attached) back into the 'cradle' in the Prenoxad Injection case. It will fit into the cradle even with the needle attached.
 - DO NOT ATTEMPT TO REMOVE OR RE-SHEATH THE NEEDLE
- 3. Call 999 and ask for an ambulance explaining that you have a casualty who is UNCONSCIOUS BUT APPEARS TO BE BREATHING
- 4. If the casualty does not wake up/regain consciousness, keep them in the recovery position and give further doses of Prenoxad Injection every 2 to 3 minutes. Inject Prenoxad Injection following the same process and using the same needle as before. Repeat this as many times as necessary until:
 - The casualty regains consciousness
 - The ambulance arrives
- 5. Stay with the casualty and continue to monitor their breathing. If there is a decrease in breathing give 0.4 ml Prenoxad Injection solution every 2 -3 minutes (if you have some left). If the casualty's breathing becomes less frequent or stops, you may need to give basic life support (see instructions on page 13).

If medical assistance has not arrived after you have used up the contents of one Prenoxad Injection syringe and you have a second Prenoxad Injection syringe available, even if it has not been prescribed to you, it may be used in the same way as the first. Using the second Prenoxad Injection in this way does not risk the person's safety.

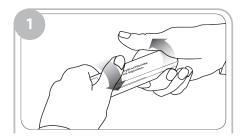


The casualty will NOT KNOW that they have been rescued from an overdosed state once they regain consciousness and may therefore be unaware of the on-going danger to them. The casualty may become agitated or even aggressive. The casualty may also want to use drugs to overcome the (almost inevitable, but temporary) withdrawal symptoms they are feeling. The casualty may even want to leave the scene BEFORE the ambulance arrives.

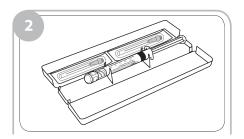
If a casualty regains consciousness/wakes up BEFORE the ambulance arrives, the helper should:

- Explain to the casualty what has happened. Tell the casualty that they overdosed, could not be woken/were having breathing problems etc.
- Offer reassurance, explaining that they have been given Prenoxad Injection to help restore their breathing and save their life
- Explain to the casualty that the withdrawal symptoms they are experiencing (if this is the
 case) are temporary and will gradually ease within the next hour or so. Also explain that
 this is because the Prenoxad Injection will wear off and that they are in danger of going
 back into overdose during this time
- The casualty should be told not to use any drugs, including alcohol
- Tell the casualty that it is extremely important that they are seen by the ambulance crew when they attend

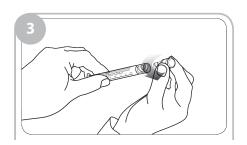
How to open, assemble and inject Prenoxad Injection



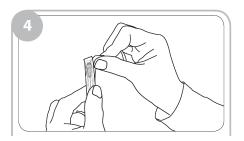
Remove the clear film wrapping by pulling the tear strip on the side of the box. Twist the outer plastic to break the tamper evident seals and open



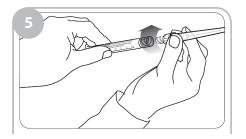
The box contains 1 syringe of Prenoxad Injection and two 23 gauge 1 ¼ inch needles for intramuscular injection



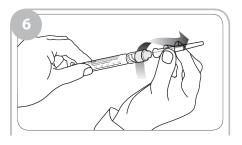
Unscrew the clear plastic top from the syringe



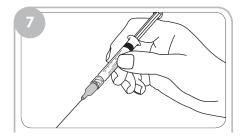
Peel back the backing paper from the needle packet and remove the needle, keeping it in its protective sheath



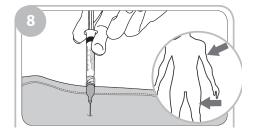
With the needle still in its sheath, screw the blue fitting onto the syringe



Gently twist the needle sheath and remove it from the syringe. It is important to twist the needle sheath instead of pulling it to avoid needle stick injury



Hold the syringe like a pen or dart



- Insert the needle at right angles (90 degrees) into the casualty's outer thigh or upper arm muscle, through clothing if necessary
- Rotate the barrel so that the black dosage line can be seen
- Inject the first dose of 0.4 ml Prenoxad Injection by holding the syringe steady and pushing the plunger to the first black line
- Take out the syringe with the needle attached and safely put it back into the case
- Do not re-sheath the needle
- If you need to give another dose, insert the syringe again and inject to the next black line
- After using Prenoxad Injection, keep the syringe in the box and hand it to the ambulance crew so that they know it has been administered

How do I dispose of Prenoxad Injection?

After you have used Prenoxad Injection, any left-over product, including used and unused needles, should be given to the attending ambulance crew.

DO NOT ATTEMPT TO REMOVE OR RE-SHEATH THE NEEDLE

If this is not possible, you should contact the service that gave you Prenoxad Injection, and report its use. The service should offer you advice, and make sure that you are re-supplied. You can dispose of the used Prenoxad Injection pack by handing it into a pharmacy or any needle exchange service.

Prenoxad Injection should not be disposed of via drains or household waste.

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How do I put someone into the recovery position?

To put someone into the recovery position, follow the steps below:

- 1. Remove the casualty's glasses (if worn)
- 2. Kneel beside the casualty and make sure that both their legs are straight
- 3. Place the arm nearest to you out at right angles to the body, elbow bent with the hand palm facing upwards
- 4. Bring the far arm across the chest, and hold the back of the hand against the casualty's cheek nearest the ground
- 5. With your other hand, grasp the far leg just above the knee and pull it up, keeping their foot on the ground
- 6. Keeping the hand pressed against the cheek, pull on the far leg to roll the casualty towards you onto their side
- 7. Adjust the upper leg so that both the hip and knee are bent at right angles
- 8. Tilt the head back to make sure the airway remains open
- 9. Adjust the hand under the cheek, if necessary, to keep the head tilted
- 10. Check their breathing regularly









How do I give chest compressions and rescue breaths (CPR) to an adult? (See video)

To carry out chest compressions:

- Place the heel of your hand on the breastbone at the centre of the casualty's chest
- Place your other hand on top of your first hand and interlock your fingers
- Lock out your arms so they are straight. You will be directly over the casualty. Press straight down by 5-6 cm on their chest

To give rescue breaths:

- Open the casualty's mouth to check if there are any obvious obstructions
- Tilt the casualty's head gently and lift the chin up with two fingers
- Pinch the casualty's nose
- Give rescue breaths by putting your mouth to theirs, making sure that your lips form a seal around the opening of their mouth, and blow steadily (see video)
- Check that their chest rises while you inflate their lungs, and falls as the air leaves their body
- Attempt to give two rescue breaths, one or two seconds apart

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What will happen immediately after injecting a dose of Prenoxad Injection and what should I do?

Prenoxad Injection may take between 1-5 minutes before it begins to work, therefore there may not be any immediate change in the casualty.

Once the medication in the Prenoxad Injection reaches the casualty's brain it will begin to work. This medication will rapidly remove any opioid drugs from opioid receptors in the casualty's brain, and temporarily 'cap' these receptors. The message from the casualty's brain to their lungs to breath, will be restored. Because of the rapid action of the medication in Prenoxad Injection, some people may start to experience withdrawal symptoms.

Once it has started working, the effects of Prenoxad Injection may last for around 20 minutes and up to one hour. Prenoxad Injection DOES NOT remove opioid drugs from the body, only from the brain receptors, thereby helping restore breathing.

Prenoxad Injection is a short acting medicine, and many of the opioid drugs often involved in overdoses last much longer in the body. This means that it is possible for the casualty to slip back into overdose. This is why it is essential to still seek medical help even if the casualty appears to be fully conscious/awake and breathing normally.

It is important that you explain to the casualty what has happened and give them reassurance. You should also tell the casualty NOT to use any other drugs (including alcohol) to overcome withdrawal symptoms if they experience them.

For these reasons, it is important that the casualty is not left alone after receiving Prenoxad Injection, even if they regain consciousness.

You should also be fully aware that Prenoxad Injection is only effective at reversing the effects of opioid drugs as mentioned before. Prenoxad Injection will have no effect on unconsciousness/breathing problems caused by any other non-opioid drug or substance, such as benzodiazepines or alcohol, which are often involved when someone overdoses.

What are the risks of taking Prenoxad Injection?

Like any medicine, Prenoxad Injection can cause side effects, although not everyone gets them. You should be aware of these possible side effects as the casualty may experience these after receiving Prenoxad Injection.

These side effects can be like withdrawal symptoms and may be due to the rapid reversal of the opioid.

Very common

(experienced by more than 1 out of every 10 people who receive Prenoxad Injection):

• Nausea (feeling sick)

Common

(experienced by more than 1 out of every 100 but less than 1 out of every 10 people who receive Prenoxad Injection):

- Dizziness
- Headache
- Faster beating of the heart
- Increased blood pressure
- Vomiting

Uncommon

(experienced by more than 1 out of every 1,000 but less than 1 out of every 100 people who receive Prenoxad Injection):

- Tremor
- Sweating
- Irregular heartbeat
- Decreased heart rate
- Diarrhoea
- Dry mouth
- Local irritation
- Inflammation
- Faster or deeper breathing

Rare

(experienced by more than 1 out of every 10,000 but less than 1 out of every 1,000 people who receive Prenoxad Injection):

- Seizure
- Tension

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Very rare

(experienced by less than 1 in 10,000 people who receive Prenoxad Injection):

• Allergic reactions (urticaria, rhinitis, dyspnoea, swelling, anaphylactic shock, cardiac arrest, redness of the skin with blisters or ulcers)

Other side effects:

- Fever
- Nervousness
- Restlessness
- Irritability
- Runny nose
- Sneezing
- Yawning
- Piloerection (goose bumps)
- Weakness
- Shivering
- Death

Who can I contact for further information?

If you have any further questions on Prenoxad Injection please contact the person who prescribed it to you, your pharmacist or local drug and alcohol treatment service.

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