

Prenoxad Injection

(naloxone hydrochloride 1mg/1ml solution for injection)

TRAINING MANUAL

Introduction

Prenoxad Injection is the first presentation of naloxone licensed for emergency use in the home or other non-medical setting by those who may witness or discover an opioid-related overdose casualty. It is used for the complete or partial reversal of respiratory depression induced by opioids. It should be carried by persons at risk of opioid overdose. The use of Prenoxad Injection in the community plays a significant role in harm reduction and drugs-related death strategies for people who use illicit/prescribed opioids.

Prenoxad Injection is a prescription only medicine and is normally supplied to a person at risk of opioid overdose, but it may be administered by anyone present at the scene of an overdose that is in a position to intervene in advance of the emergency services attending. It can also be supplied to the friends, family or other representative of someone identified as at risk, but only with the written consent from the person for whom it is to be supplied.

Because it may be used in a non-medical setting, Prenoxad Injection will only be prescribed when the prescriber has assessed the suitability, competence and understanding of a client or their representative to appropriately administer Prenoxad Injection to a casualty experiencing a suspected opioid or opioid-related overdose event. This may be satisfied by the prescriber training the client or representative themselves or by demonstration that the training has been completed elsewhere.

This training manual will guide you through how to train a client and/or their representative on Prenoxad Injection, so they gain the knowledge and skills to administer it and provide appropriate aftercare. When completed, the level of training should satisfy prescribers that the client and/or representative is suitable, competent and clearly understands how to correctly administer Prenoxad Injection in the appropriate circumstances.

Training can be delivered in a variety of settings, and sometimes in one-to-ones as well as group settings. This, along with the clients' prior learning about opioid and opioid-related overdose can greatly influence how long may be required to deliver the training. Experience across the UK has shown that effective training may take anywhere from 20 minutes for an individual to 2-3 hours for groups.

This training manual does not include guidance on overdose prevention, risk factors for overdose or high risk times for overdose.

How to use the training manual

The training manual is split into the sections listed below. You should talk through each of these sections with the client and/or representative. Some of the sections include demonstrations or other materials to use; these are described in detail in the relevant sections.

At the end of each section you should ask the client and/or representative whether they understand what you have discussed and ask them if they have any questions.

- 1. What Prenoxad Injection is and what it is used for
 - About Prenoxad Injection and what it does
 - What Prenoxad Injection doesn't do
- 2. How to get Prenoxad Injection
 - Who can get Prenoxad Injection
 - How to get Prenoxad Injection
 - Who can use Prenoxad Injection
- 3. When to use Prenoxad Injection
- 4. How to assemble and inject Prenoxad Injection
 - What's in the pack
 - How to assemble and how and when to inject Prenoxad Injection
 - How and when to inject Prenoxad Injection
 - · How and when to phone an ambulance
- 5. How to store and dispose of Prenoxad Injection
 - How to store Prenoxad Injection
 - How to dispose of Prenoxad Injection
- 6. How to put someone into the recovery position
- 7. How to give chest compressions and rescue breaths (CPR) to an adult
- 8. What may happen immediately after injecting a dose of Prenoxad Injection and what to do
- 9. What the risks of taking Prenoxad Injection are
- 10. Who to contact for further information

You may also want to use the videos found on www.prenoxadinjection.com to support the training.

You should give the client and/or representative a copy of the Patient Information Leaflet and the Client's Guide to Prenoxad Injection to take away with him or her. These cover the information that will have been discussed in the training and can be referred to by the client and/or representative after the training.

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The brochure also includes a Prenoxad Injection Training checklist. At the end of the training, fill in a copy of the checklist to confirm that the training has been completed and that the client and/or representative understands when and how to correctly and appropriately administer Prenoxad Injection.

Materials you need:

- Copy of the Client's Guide to Prenoxad Injection
- Copy of the Patient Information Leaflet
- Copy of the Training Checklist
- Demonstration/sample packs of Prenoxad Injection (if available)
- Oranges to demonstrate injection of Prenoxad Injection (if demonstration/sample packs available)
- Resuscitation dummy to demonstrate rescue breaths and chest compressions (CPR) (if available)

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1. What Prenoxad Injection is and what it is used for

Training instructions:

Talk through the content below with the client and/or representative.

About Prenoxad Injection and what it does

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.

What Prenoxad Injection doesn't do

Prenoxad Injection does not:

- Remove the opioids from the body
- Get a person high or stoned
- Have an effect on alcohol, cocaine, speed, ecstasy or benzodiazepines (e.g., valium)
- Does not last indefinitely
 - It wears off after around 20-30 minutes so the opioids will still be in the body and the person may go back into overdose
- Have an effect unless the person has opioids in their system

Training instructions:

2. How to get Prenoxad Injection

Training instructions:

Talk through the content below with the client and/or representative.

Who can get Prenoxad Injection

Prenoxad Injection is a prescription only medicine, which means that it can only be supplied to someone who has a prescription for it.

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.

How to get Prenoxad Injection

To get Prenoxad Injection you need to show that you understand how and when to use it. The prescriber will need to be sure that you understand when and how to use Prenoxad Injection before he or she prescribes it. Your representative may also be trained on using Prenoxad Injection. This is why this training is important. The prescriber may want to check your understanding or carry out their own training before they give you a prescription.

Who can use Prenoxad Injection

Although Prenoxad Injection is a Prescription Only Medicine (POM), the law allows anyone to administer it for the purpose of saving a life. This means that your representative, or other family member or friends can inject Prenoxad Injection.

It is important that you always carry your Prenoxad Injection with you and tell your representative and other family or friends where they can find it in an emergency.

Training instructions:

3. When to use Prenoxad Injection

Training instructions:

Talk through the content below with the client and/or representative. You can also use the 'Identify opioid overdose' video on the www.prenoxadinjection.com website

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.

Training instructions:

4. How to assemble and how and when to inject Prenoxad Injection

Training instructions:

Talk through the content below with the client and/or representative, referring to the Client's Guide to Prenoxad Injection to show illustrations. If you have demonstration/sample packs of Prenoxad Injection you should use it as described below.

What's in the pack

Training instructions:

If you have a demonstration/ sample pack of Prenoxad Injection, demonstrate as below.

The Prenoxad Injection pack contains a glass 2 ml syringe containing a clear and colourless solution of naloxone. The pack also contains two 1 ¼ inch needles. Two needles are included in case one breaks or gets contaminated (e.g. if it gets dropped).

There will also be a patient information leaflet supplied by the manufacturer which gives instructions on how to assemble and use Prenoxad Injection.

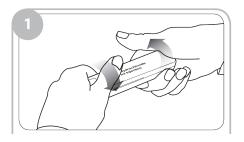
How to assemble and inject Prenoxad Injection

Training instructions:

If you have demonstration/sample packs of Prenoxad Injection, demonstrate how to assemble and inject Prenoxad Injection, according to the description below.

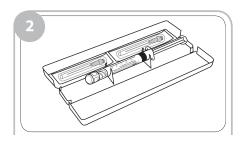
- 1. In real time and with no description, open and assemble Prenoxad Injection and demonstrate administering Prenoxad Injection. Use an orange to demonstrate injection technique, but indicate on your thigh or upper arm where the injection would be given in a real situation
- 2. Repeat the above, but this time talk through the process
- 3. Repeat again, this time with the client and/or representative explaining what to do
- 4. Allow the client and/or representative to practice opening, assembling and injecting Prenoxad Injection

If you do not have a demonstration/sample pack, use the Client's Guide to Prenoxad Injection to talk through the steps below. You can also use the 'Injecting Prenoxad Injection' on the www.prenoxadinjection.com website.

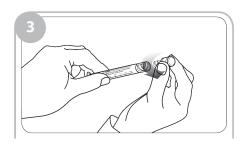


Remove the clear film wrapping by pulling the tear strip on the side of the box.

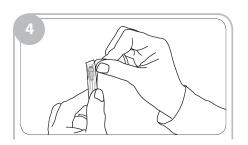
Twist the outer plastic to break the tamper evident seals and open



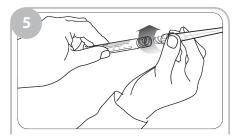
The box contains 1 syringe of Prenoxad Injection and two 23 gauge 1 ¼ inch needles for intramuscular injection



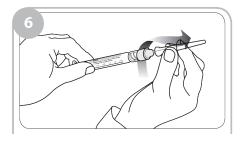
Unscrew the clear plastic top from the syringe



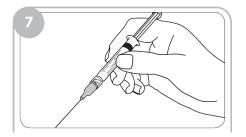
Peel back the backing paper from the needle packet and remove the needle, keeping it in its protective sheath



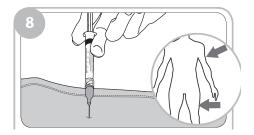
With the needle still in its sheath, screw the blue fitting onto the syringe



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 and when to inject Prenoxad Injection

Training instructions:

Use the Client's Guide to Prenoxad Injection to use the flowchart and talk through the steps below.

You can also use the video on the www.prenoxadinjection.com website.

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 shouting at the casualty.

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
- 3. Give 0.4 ml Prenoxad Injection:
 - Open and assemble Prenoxad Injection
 - 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, 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. 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
- 2. Give 0.4 ml Prenoxad Injection:
 - Open and assemble Prenoxad Injection
 - 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, 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
- 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 i.e. hold the syringe like a pen, inject at a right angle to the surface of the skin and push the plunger down to the next black line. 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.

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.

Person unconscious and unresponsive Identify opioid overdose DO NOT DO Shout for help and approach with care - Inflict pain Move them onto their back if necessary - Put them in a bath or shower - Walk them about - Use other drugs such Open airway: as stimulants Tilt head back gently and lift chin - Leave them alone Check breathing NOT BREATHING **BREATHING Call 999** Recovery position Inject 0.4 ml Prenoxad 30 chest compressions then 2 rescue breaths Injection (to first black line) Inject 0.4 ml Prenoxad **Call 999** Injection (to first black line) If no change after 2-3 minutes Still not breathing Inject 0.4 ml Prenoxad Give 3 cycles of Injection (to next black line) 30 chest compressions then 2 rescue breaths and inject 0.4 ml Prenoxad Injection (to next black line) If the casualty stops breathing at any time, move them onto their back and. **Breathing** Casualty regains **Recovery position** consciousness 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

Training instructions:

Ask the client and/or representative if he or she understands. Check if he or she has any questions.

How and when to phone an ambulance

Training instructions:

Talk through the content below with the client and/or representative.

If the casualty is not breathing you should call an ambulance immediately. If the casualty is breathing, you should call an ambulance after you have moved the person into the recovery position and administered the first dose of Prenoxad Injection.

To call an ambulance:

- Make sure that you are calm and it's not too noisy where you are
- Dial 999
- Calmly ask for an ambulance
- Explain that you have a casualty who you think has overdosed on opioids
- Tell the call handler the status of the casualty for example, if they are breathing, not breathing or unconscious
- Answer any questions you are asked as fully as possible

Stay with the person until the ambulance crew arrives. Tell them what has happened and give them any relevant powders or pills.

If you have used Prenoxad Injection, hand it to the ambulance crew so that they know it has been administered.

Training instructions:

5. How to store and dispose of Prenoxad Injection

Training instructions:

Talk through the content below with the client and/or representative.

How to store Prenoxad Injection

Prenoxad Injection should be kept out of sight and reach of children. It should be stored in the original box to protect from light. It should not be stored above 25°C.

If the injection is discoloured it should not be used.

How to 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 in to a pharmacy or any needle exchange service.

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

Training instructions:

6. How to put someone into the recovery position

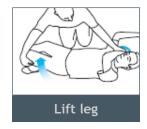
Training instructions:

Use the Client's Guide to Prenoxad Injection to talk through the steps below. Demonstrate how to put someone into the recovery position using the client or representative as the casualty. Allow the client and/or representative to practice using you as the casualty. You can also use the 'Recovery Position' video on the www.prenoxadinjection.com website.

- 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









Training instructions:

7. How to give chest compressions and rescue breaths (CPR) to an adult

Training instructions:

Use the Client's Guide to Prenoxad Injection to talk through the steps below. If you have a resuscitation dummy, demonstrate how to perform chest compressions and rescue breaths on the resuscitation dummy. Allow the client and/or representative to practice using the resuscitation dummy. You can also use the 'Performing CPR' video on the www.prenoxadinjection.com website.

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

Training instructions:

8. What may happen immediately after injecting a dose of Prenoxad Injection and what to do

Training instructions:

Talk through the content below with the client and/or representative. Stress the following points:

- There is a danger of overdose symptoms returning when the Prenoxad Injection wears off
- The casualty must not be left alone after Prenoxad Injection has been administered
- The casualty must get medical treatment as soon as possible
- The casualty must not use any other substances after Prenoxad Injection has been administered
- The severity and duration of withdrawal symptoms are related to the dose of Prenoxad Injection given and to the degree and type of opioid dependence

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 cause by any other non-opioid drug or substance, such as benzodiazepines or alcohol, which are often involved when someone overdoses.

Training instructions:

9. What the risks of taking Prenoxad Injection are

Training instructions:

Use the Client's Guide to Prenoxad Injection to talk through the content below. Explain that these side effects can be like withdrawal symptoms and may be due to the rapid reversal of the opioid.

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.

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

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

Training instructions:

10. Who to contact for further information

Training instructions:

Talk through the content below with the client and/or representative.

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.

Training instructions:

Ask the client and/or representative if he or she understands. Check if he or she has any questions.

Training instructions:

After completing the training, fill in and sign a copy of the Prenoxad Injection Training Checklist for the client or representative to take with them. Advise them where they can get a prescription and collect their Prenoxad Injection from. Make sure the client or representative also takes a copy of the Patient Information Leaflet and the Client's Guide to Prenoxad Injection to take away with him or her.

Prenoxad Injection (naloxone hydrochloride 1mg/1ml solution for injection)

Training Checklist

Name:	GP Name:	
Date of Birth:	Address:	
Address:		
Post Code		
		Trainer Initials
What Prenoxad Injection is, what it does and what	it doesn't do	
The signs/symptoms of suspected opioid overdose Pinpoint pupils; breathing problems; pale skin colour; tip of nose, eye bags, fingertips or nails; no response loss of consciousness		
How to assemble Prenoxad Injection		
How to inject Prenoxad Injection In a casualty who is breathing and unconscious: put the recovery position and administer one dose (0.4 ml) of 2-3 minutes until the casualty regains consciousness of	Prenoxad Injection every	
In a casualty who is not breathing: give 30 chest comp breaths then administer one dose (0.4 ml) of Prenoxa of three times 30 chest compressions and 2 rescue bre Prenoxad Injection until the casualty begins breathing	d Injection. Repeat cycles eaths and one dose of	
When to call 999 If the casualty is not breathing an ambulance should be to been moved into the recovery position and the first dadministered	called after the person has	
How to put a casualty into the recovery position		
How to perform chest compressions and rescue breaths 30 compressions followed by 2 rescue breaths		
Naloxone is short acting The effects of naloxone wear off after 20-30 minutes overdose may return	and the possibility that	
The importance of staying with the person The casualty should not be left alone or allowed to us they regain consciousness	se any other drugs if	
I confirm that the above client/representative has dem the appropriate use of Prenoxad Injection.	onstrated an understanding	g of
Trainer Name:	Trainer Signature:	
Service Name & Address:		
	Date:	

Prescribing information for Prenoxad 1mg/ml Injection

Please refer to Summary of Product Characteristics before prescribing.

Presentation: A 2ml pre-filled syringe containing Naloxone Hydrochloride 1mg/ml.

Indications: Prenoxad Injection is intended for emergency use in the home or other non-medical setting by appropriate individuals or in a health facility setting for the complete or partial reversal of respiratory depression induced by natural and synthetic opioids, including methadone, diamorphine (diacetylmorphine (INN)) and certain other opioids such as dextropropoxyphene and certain mixed agonist/antagonist analgesics: nalbuphine and pentazocine. Prenoxad Injection should be carried by persons at risk of such events. It may also be used for the diagnosis of suspected acute opioid overdose.

Dosage and Administration: Prenoxad Injection may only be made available once the prescriber has assessed the suitability and competence of a client or representative to administer Naloxone in the appropriate circumstances. Prenoxad Injection is for administration by intramuscular injection.

Adults and the Elderly, Opioid overdosage (known or suspected). For Use by individuals in the community. In patients where breathing does not appear to be normal: In patients where breathing does not appear to be normal administration of Prenoxad Injection should be preceded by calling emergency services and requesting an ambulance. Following this, 30 chest compressions and if possible 2 rescue breaths (Basic Life Support SINGLE CYCLE) should be given; 0.4ml Prenoxad Injection solution should then be administered by intramuscular injection into the outer thigh muscle or muscles of the upper arm, through clothing if necessary. A further 3 cycles of chest compressions and rescue breaths should then be given followed by administration of 0.4ml Prenoxad Injection. Three cycles of chest compression and rescue breaths should take approximately 2 minutes. This should be repeated until an ambulance arrives or the patient begins breathing normally / regains consciousness. The patient when breathing normally or has regained consciousness should be placed in the recovery position (lying on their side, mouth open pointing towards the ground) and observed continuously.

In patients where breathing is normal but the patient is unrousable or suspected to be unconscious:

The patient should be placed in the recovery position. 0.4ml Prenoxad Injection solution should be administered by intramuscular injection into the outer thigh muscle or muscles of the upper arm, through clothing if necessary, and an ambulance should be called. 0.4ml Prenoxad Injection solution should then be administered every 2-3 minutes and continued until the ambulance arrives and or the patient regains consciousness.

Children and Neonates: The Prenoxad Injection presentation is not intended to be used for children in the home setting other than by an appropriately trained healthcare professional.

Contra-Indications: Known hypersensitivity to Naloxone or any of the ingredients.

Warnings and Precautions: Prenoxad Injection is intended as an emergency treatment and the patient should be advised to seek medical help immediately.

It should be administered cautiously to patients who have received large doses of opioids or to those physically dependent on opioids since too rapid reversal of opioid effects by Prenoxad may precipitate an acute withdrawal syndrome in such patients. Patients who have responded satisfactorily to Prenoxad should be kept under medical observation for at least 2 hours. Repeated doses of Prenoxad may be necessary since the duration of action of some opioids may exceed that of Prenoxad. Use with caution in patients with pre-existing cardiac, hepatic or renal disease and in those receiving medications with potential adverse cardiovascular effects e.g. hypotension, ventricular tachycardia or fibrillation and pulmonary oedema. Caution should be exercised and patients monitored when Prenoxad Injection is administered to this patients with renal insufficiency/failure or liver disease.

Interactions: Administer cautiously to opioid dependent patients including newborns of mother's dependant or those suspected of having received large doses and observe for signs of acute withdrawal.

Pregnancy and Lactation: Prenoxad should be used with caution in pregnancy. The neonate must also be monitored for signs of opioid withdrawal. Naloxone may be administered during the second stage of labour to correct any respiratory depression due opioid analgesics. It is not known whether Naloxone is excreted in human milk therefore use with caution in breastfeeding mothers.

Undesirable Effects: Common side effects include nausea, vomiting, dizziness, headache, ventricular tachycardia, hypotension and hypertension.

Less common side effects: Tremor, sweating, arrhythmia, bradycardia, diarrhoea, dry mouth, hyperventilation, inflammation. Seizure tension, allergic reactions, anaphylactic shock, fibrillation, cardiac arrest, erythema multiforme, fever, dyspnoea, runny nose, sneezing and yawning. Piloerection, weakness, shivering.

Product Licence Number: PL 12064/0125 Product Licence Holder: Aurum Pharmaceuticals Ltd, Bampton Road, Harold Hill, Romford, Essex RM3 8UG Basic NHS Price: £18.00

Legal Category: POM.

Date of Preparation: April 2013

For more details contact: Aurum Pharmaceuticals Hubert Road, Brentwood, Essex CM14 4LZ

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Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Martindale Pharma Tel. 01277 266600
Fax 01708 382739
e-mail drugsafety@martindalepharma.co.uk

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