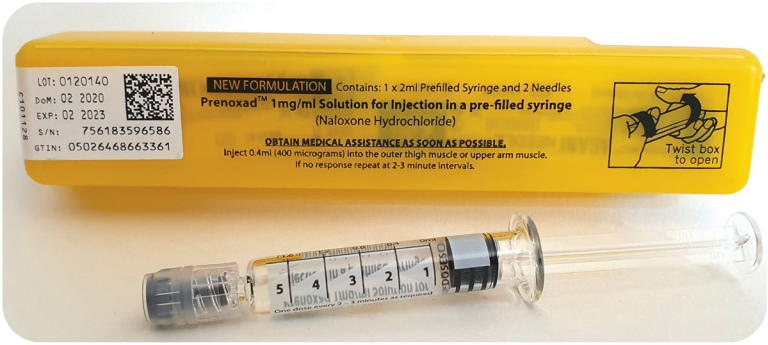
Training Checklist

Prenoxad®Injection

(naloxone hydrocholoride 1mg/ml solution for intramuscular injection)



This Training Checklist can be used to help with delivery of 'refresher' training, and when making first or replacement supplies of Prenoxad Injection.

Please review your organisational or other local authority training and supply protocols, and be familiar with the Prenoxad Injection Summary of Product Characteristics (SmPC) before making supplies.

Please also be sure to have copies of the 'Prenoxad Injection client guide', so that it may be issued alongside a kit.

For more information go to www.prenoxadinjection.com

Date of Approval: 18-Feb-2021 Version: 3.0

Prescribing Information for Prenoxad (naloxone hydrochloride) 1mg/ml Solution for Injection in a prefilled syringe.
Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: A sterile, clear and colourless liquid in a 2ml prefilled syringe, each 1 ml of solution contains 1 mg of naloxone hydrochloride. **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 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 is for administration by intramuscular injection.** 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 administered as a part of a resuscitation intervention in suspected overdose casualties, where opioid drugs may be involved or suspected. It may need to be used in a non-medical setting. The prescriber should take appropriate steps to ensure that the patient thoroughly understands the indications and use of Prenoxad Injection. The prescriber should review with the patient or any other person who might be in a position to administer Prenoxad Injection to a patient experiencing a suspected opioid overdose event. **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:** Patient should be placed in the recovery position (lying on their side, mouth open pointing towards the ground). 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. The patient should be continuously observed but particularly their breathing. If there is a decrease in breathing it is important that 0.4ml Prenoxad Injection solution is given every 2 -3 minutes. Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration whenever solution and container permit. **Adults: Opioid overdosage (known or suspected). Use by individuals in the community.** 400 micrograms or 0.4ml of Prenoxad Injection solution by intramuscular injection into the outer thigh or muscles of the upper arm as part of the resuscitation intervention. The dose of 0.4ml can be repeated every 2-3 minutes in subsequent resuscitation cycles until the contents of a syringe are used up. The duration of action of certain opioids can outlast that of an IV bolus of Naloxone, e.g. dextropropoxyphene, dihydrocodeine and methadone. In situations where one of these opioids is known or suspected it is recommended that an infusion of Naloxone be used to produce sustained antagonism to the opioid without repeated injection. **Children:** The Prenoxad Injection presentation is not intended to be used for children in the home setting other than by an appropriately trained healthcare professional. In the event of a child being given or taking an opioid inappropriately an ambulance should be called and resuscitation started if required. **Neonatal Use:** Naloxone should only be used in Neonates under medical supervision. **Elderly:** Use as for adults. Consult SmPC for further information. **Contra-Indications:** Known hypersensitivity to Naloxone or any of the excipients. **Warnings and Precautions:** Patients muct be instructed in the proper use of Prenoxad Injection (see above). 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. The same caution is needed when giving Prenoxad to neonates delivered to such patients. Hypertension, cardiac arrhythmias, pulmonary oedema and cardiac arrest have been described. For signs and symptoms of opioid withdrawal in a patient physically dependent on opioids please see SmPC. 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. Prenoxad Injection is not effective against respiratory depression caused by non-opioid drugs. Reversal of buprenorphine-induced respiratory depression may be incomplete. If an incomplete response occurs, respiration should be mechanically assisted. Abrupt postoperative reversal of opioid depression may result in nausea, vomiting, sweating, tremulousness, tachycardia, increased blood pressure, seizures, ventricular tachycardia and fibrillation, pulmonary oedema and cardiac arrest which may result in death. Several instances of hypotension, hypertension, ventricular tachycardia and fibrillation, pulmonary oedema and cardiac arrest have been reported in postoperative patients. Death, coma and encephalopathy have been reported as sequel of these events. Although a direct cause and effect relationship has not been established, Prenoxad should be used with caution in patients with pre-existing cardiac 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 patients with renal insufficiency/failure or liver disease. Consult SmPC for further information. **Interactions:** The effect of naloxone hydrochloride is due to the interaction with opioids and opioid agonists. When administered to subjects dependent on opioids, in some subjects the administration of naloxone hydrochloride can cause pronounced withdrawal symptoms. Hypertension, cardiac arrhythmias, pulmonary oedema and cardiac arrest have been described. With a standard naloxone hydrochloride dose there is no interaction with barbiturates and tranquillizers. Data on interaction with alcohol are not unanimous. In patients with multi intoxication as a result of opioids and sedatives or alcohol, depending on the cause of the intoxication, one may possibly observe a less rapid result after administration of naloxone hydrochloride. When administering naloxone hydrochloride to patients who have received buprenorphine as an analgesic complete analgesia may be restored. It is thought that this effect is a result of the arch-shaped dose-response curve of buprenorphine with decreasing analgesia in the event of high doses. However, reversal of respiratory depression caused by buprenorphine is limited. Severe hypertension has been reported on administration of naloxone hydrochloride in cases of coma due to a clonidine overdose. **Pregnancy and Lactation:** Pregnancy: The safety of this medicinal product for use in human pregnancy has not been established. Animal studies have shown reproductive toxicity. The potential risk for humans is unknown, therefore, Prenoxad should not be used during pregnancy unless clearly necessary. In a pregnant woman who is known or suspected to be opioid-dependent, risk benefit must be considered before Prenoxad Injection is administered, since maternal dependence may be accompanied by foetal dependence. In this type of circumstance, the neonate should be monitored for respiratory rate and signs of opioid withdrawal. *Use in labour and delivery:* Prenoxad may be administered to mothers during the second stage of labour to correct any respiratory depression caused by opioids used to provide obstetrical analgesia. It is not known if Naloxone affects the duration of labour and/or delivery. *Breast-feeding:* It is not known whether Naloxone is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised when Prenoxad Injection is administered to a nursing mother. Therefore, breast-feeding should be avoided in the first 24 hours after treatment. **Effects on ability to drive and use machines:** Patients who have received Prenoxad to reverse the effects of opioids should be warned to avoid road traffic, operate machinery or engage in other activities demanding physical or mental exertion for at least 24 hours, since the effect of the opioids may return. **Undesirable Effects: Consult SmPC for the full list of undesirable effects.** *Very common (≥1/10): nausea. Common (≥1/100 to <1/10):* dizziness, headache, tachycardia, hypotension, hypertension and cardiac arrhythmia (including ventricular tachycardia and fibrillation) have also occurred with the postoperative use of naloxone hydrochloride. Adverse cardiovascular effects have occurred most frequently in postoperative patients with a pre-existing cardiovascular disease or in those receiving other drugs that produce similar adverse cardiovascular effects. Vomiting. Postoperative pain. **Overdose:** There is limited clinical experience with Naloxone overdosage in humans. Consult SmPC for management guidance. **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. **Further information:** Martindale Pharma, Bampton Road, Romford, RM3 8UG. Tel: 01277 266 600. **Date of Preparation:** July 2021.

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 266 600.
e-mail. drugsafety.uk@ethypharm.com

Ethypharm

Training Checklist

Name of person being trained and/ or supplied:		Treatment or support service name:	
DOB:		Treatment or support service address:	
Address and postcode:			

Applicable if this is different from the service issuing the Prenoxad Injection kit

Briefly talk through each item below with the person being trained or supplied with Prenoxad® Injection. Key training messages are in italics. You can also refer to the Client Guide and website for more information if you need it.	Does the person being supplied understand this?
Talk through what Prenoxad® is, what it does and what it doesn't do • Prenoxad® contains naloxone which is an opioid antagonist, meaning it reverses the effect of opioids only. For this reason, it's used in suspected opioid overdoses. • It is short acting and wears off after 20 mins to 1 hour • It has NO EFFECT on benzos or alcohol • It will only temporarily restore breathing	Yes / No
Discuss the signs/symptoms of suspected opioid overdose Pinpoint pupils; breathing problems; pale skin colour; bluish tinge to lips, tip of nose, fingertips or nails; no response to noise or touch; loss of consciousness	Yes / No
When to call the emergency services If the casualty is not breathing an ambulance should be called immediately. If the casualty is breathing, an ambulance should be called after the person has been moved into the recovery position and the first dose of Prenoxad® Injection administered	Yes / No
How to assemble Prenoxad® *(Reminder: You can use the 'how to' videos on Prenoxadinjection.com)* 1. Remove wrapper and twist box to break seal 2. Unscrew top from syringe 3. Remove needle from paper packet 4. Screw the needle and syringe together 5. Twist the needle sheath to remove it	Yes / No
How to inject Prenoxad® (Prenoxad is administered by intramuscular (IM) injection) *(Reminder: You can use the 'how to' videos on Prenoxadinjection.com)* In a casualty who is breathing and unconscious: put the casualty into the recovery position and administer one **IM** dose (to the black line) of Prenoxad® Injection every 2-3 minutes until the casualty regains consciousness or the ambulance arrives In a casualty who is not breathing: give 30 chest compressions and 2 rescue breaths (one cycle) then administer one **IM** dose of Prenoxad® Injection. Now give 3 cycles of 30 chest compressions and two rescue breaths, followed by the next **IM** dose of Prenoxad Injection. Repeat this - 3 cycles, 1 dose of Prenoxad® Injection - until the casualty responds or the ambulance arrives.	Yes / No

	Appropriate answer?
How to put a casualty into the recovery position *(Reminder: You can use the 'how to' videos on Prenoxadinjection.com)* 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 (say 'HI') 4. Bring the far arm across the chest, and hold the back of the hand against the casualty's cheek nearest the ground (support face) 5. With your other hand, grasp the far leg just above the knee and pull it up, keeping their foot on the ground (lift leg) 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 (roll over) 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	Yes / No
How to perform chest compressions and rescue breaths *(Reminder: You can use the 'how to' videos on Prenoxadinjection.com)* 30 compressions followed by 2 rescue breaths • Place your other hand on top of your first hand and interlock your fingers • Place the heel of your hand on the breastbone at the centre of the casualty's chest • 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 • 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 • Check that their chest rises while you inflate their lungs, and falls as the air leaves their body	Yes / No
Please explain Prenoxad® (Naloxone) is short acting The opioid overdose reversal effects of Prenoxad® Injection may begin to wear off after 20-30 mins. Although unlikely, it is possible for a casualty to re enter an overdose. This reinforces the need for medical attention following overdose.	Yes / No
Please discuss the importance of staying with the overdose casualty Stay with the casualty, and try to make sure they are not left alone during or following overdose. If the casualty regains consciousness, it's vital that they don't use any drugs including alcohol.	Yes / No
I can confirm that the person named above has demonstrated an understanding of the appropriate use of Prenoxad® Injection.	

Trainer/Issuer's name:		Date:	
Issuing Service provider/ organisation name, if different from above:		Trainer/Issuer's Signature:	

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