Prenoxad® Injection

····· naloxone hydrochloride

Prenoxad Injection

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

PRESCRIBER'S GUIDE

Prescribing information can be found on the last page

Dear Prescriber,

Prenoxad Injection is a form of naloxone intended 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. Its use in the community plays a significant role in harm reduction and drugs-related death strategies for people who use illicit/ prescribed opioids.

The purpose of this brochure is to provide additional information on the safe and appropriate prescribing of Prenoxad Injection including:

1. Indication and prescribing
2. Administration
3. Warnings
4. Disposal
5. What to consider before prescribing Prenoxad Injection
6. Prescribing checklist
7. List of additional resources

It summarises important information from the Summary of Product Characteristics (SmPC) but is not intended to replace it. Before prescribing Prenoxad Injection for the first time, please read the following information.

1. Indication and prescribing[1]

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. Prenoxad Injection is administered as a part of a resuscitation intervention in suspected overdose casualties, where opioid drugs may be involved or suspected, so it should be carried by persons at risk of such events.

Natural and synthetic opioids include methadone, diamorphine (dicetylemorphine (INN) or heroin) and certain other opioids such as dextropropoxyphene and certain mixed agonist/antagonist analgesics such as nalbuphine and pentazocine.

Prenoxad Injection is not effective against respiratory depression caused by non-opioid drugs.

Because it may be used in a non-medical setting, you should ensure that the client or any other person who might be in a position to administer Prenoxad Injection to someone experiencing a suspected opioid or opioid-related overdose event is competent, suitable and thoroughly understands when and how to use Prenoxad Injection. You may deliver training yourself by talking the client or representative through the ‘Client’s Guide to Prenoxad Injection’ or you may be satisfied if it can be demonstrated that the training has been completed elsewhere.

2. Administration[1]

Before administration, visually inspect Prenoxad Injection for particulate matter and discolouration.

Adults and elderly

Known or suspected opioid overdose where breathing does not appear to be normal

- Call emergency services and request an ambulance
- Give 30 chest compressions and if possible 2 rescue breaths (Basic Life Support SINGLE CYCLE)
- Administer 0.4 ml Prenoxad Injection solution 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 0.4 ml Prenoxad Injection
- 3 cycles of chest compression and rescue breaths should take approximately 2 minutes. This should be repeated until an ambulance arrives or the casualty begins breathing normally or regains consciousness
- When the casualty is breathing normally or has regained consciousness, he or she should be placed in the recovery position (lying on their side, mouth open pointing towards the ground) and observed continuously

Known or suspected opioid overdose where breathing is normal but the casualty is unrousable or suspected to be unconscious

- Place casualty in the recovery position (lying on their side, mouth open pointing towards the ground)
- Administer 0.4 ml Prenoxad Injection solution by intramuscular injection into the outer thigh muscle or muscles of the upper arm, through clothing if necessary
- Call emergency services and request an ambulance
- Administer 0.4 ml Prenoxad Injection solution every 2-3 minutes until the ambulance arrives or the casualty regains consciousness
- Continuously observe the casualty, particularly their breathing. If there is a decrease in breathing give 0.4 ml Prenoxad Injection solution every 2 -3 minutes

Use by individuals in the community

400 micrograms or 0.4 ml of Prenoxad Injection solution should be administered by intramuscular injection into the outer thigh or muscles of the upper arm as part of the resuscitation intervention. The dose of 0.4 ml can be repeated every 2-3 minutes in subsequent resuscitation cycles until the contents of a syringe are used up.

Use in children and neonates

Prenoxad Injection 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. Naloxone should only be used in neonates under medical supervision.

3. Warnings[1]

Contraindications
Prenoxad Injection should not be given to clients who are known to be hypersensitive to the drug or any of the ingredients.

Requesting medical attention
Prenoxad Injection is intended as an emergency treatment and the client and/or any other person who might be in a position to administer should be advised to seek medical help immediately. Patients who have responded satisfactorily to Prenoxad Injection should be placed under medical supervision and kept under observation for at least 2 hours. The client and/or representative should be advised that the person who administers Prenoxad Injection should not leave the casualty.

Opioid withdrawal
Too rapid reversal of opioid effects by Prenoxad Injection may precipitate an acute withdrawal syndrome. Therefore, Prenoxad Injection should be administered cautiously to those who have received large doses of opioids or to those physically dependent on opioids. The signs and symptoms of opioid withdrawal in a patient physically dependent on opioids may include, but are not limited to, the following: body aches, diarrhoea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea, vomiting, nervousness, restlessness, irritability, shivering, trembling, abdominal cramps, weakness and increased blood pressure. In the neonate, opioid withdrawal may also include: convulsions, excessive crying and hyperactive reflexes.

Delayed respiratory depression
The duration of action of some opioids may exceed that of Prenoxad Injection, requiring repeated doses. Therefore, casualties who have responded satisfactorily to Prenoxad Injection should be placed under medical supervision and kept under observation for at least 2 hours.

Lack of effect in mixed overdose
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.

Use in renal insufficiency and liver disease
The safety and effectiveness of Prenoxad Injection in patients with renal insufficiency/failure or liver failure have not been established in clinical trials. Caution should be exercised and patients monitored when Prenoxad Injection is administered to these populations.

4. Disposal[1]

Prenoxad Injection is intended for use for one patient only and any remaining solution should be discarded after use. Any used product should be given to the ambulance crew at the scene of the overdose, handed into a local pharmacy or needle exchange for disposal or returned to the service from where it was dispensed. The needle should not be removed or re-sheathed.

5. What to consider before prescribing Prenoxad Injection

- Before prescribing, ensure that you are familiar with the Prenoxad Injection SmPC (available at www.prenoxadinjection.com)
- Please familiarise yourself with when and how to administer Prenoxad Injection and ensure you are able to explain this to clients or representatives if needed
- Ensure that the client or any other person who might be in a position to administer Prenoxad Injection thoroughly understands the indications and proper use[1]
  - If you do not perform the training yourself you should be satisfied that the training has been completed elsewhere before prescribing
- Please talk through the comprehensive Client's Guide to Prenoxad Injection with clients and their representative and make sure they take a copy with them
  - If you do not do this yourself you should be satisfied that it has been completed elsewhere and the client has a copy
- Please use the checklist for prescribers (in section 6)

6. Prescribing checklist

Required actions before Prenoxad Injection is prescribed:

1. Assess suitability and competence of a client or representative to administer Prenoxad Injection in the appropriate circumstances[1]
2. Ensure client or any other person who might be in a position to administer Prenoxad Injection clearly understands when and how to use Prenoxad Injection[1]
3. Client and/or representative has been given instructions on:
   - How to recognise an opioid overdose
   - How to perform CPR
   - How to assemble Prenoxad Injection
   - How to administer Prenoxad Injection
4. Client and/or representative is familiar with the Client's Guide to Prenoxad Injection and takes a copy with them
5. Client and/or representative is aware of what may happen after administration and understand the need for immediate medical assistance
6. Client and/or representative understands the need to inform representative, family and/or friends of when and how to use Prenoxad Injection and where it can be found
7. Client and/or representative understands how to correctly dispose of Prenoxad Injection
8. Client and/or representative is familiar with the Patient Information Leaflet and takes a copy with them

Points 2 to 7 may be achieved by talking through the comprehensive Client's Guide to Prenoxad Injection with clients and their representatives and ensuring they take a copy with them.

7. List of additional Resources

The following additional guides have been developed:

- Client's Guide to Prenoxad Injection (naloxone hydrochloride 1mg/1ml solution)
- Pharmacist's Guide to dispensing Prenoxad Injection (naloxone hydrochloride 1mg/1ml solution)
- Training Manual for Prenoxad Injection (naloxone 1 mg/ml)

These are available on the Prenoxad Injection website (www.prenoxadinjection.com).
This material can also be requested from
Martindale Pharma's Medical Information Department:
medinfo@martindalepharma.co.uk

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
01277 266600

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

REFERENCES
1. Prenoxad Injection Summary of Product Characteristics (SmPC)

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