Prenoxad® Injection

····· naloxone hydrochloride

Prenoxad Injection

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

PHARMACIST'S GUIDE

Prescribing information can be found on the last page

Dear Pharmacist,

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 dispensing of Prenoxad Injection including:

1. Indication and prescribing
2. Administration
3. Disposal
4. What to consider before dispensing Prenoxad Injection
5. Dispensing Prenoxad Injection
6. List of additional resources

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

1. Indication[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, 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.

2. Administration[1]

Adults and elderly

- 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

- 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

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.

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. 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.

4. What to consider before dispensing Prenoxad Injection

- Before dispensing, ensure that you are familiar with the Prenoxad Injection Summary of Product Characteristics (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 required
- Ensure that the client and any other person who might be in a position to administer Prenoxad Injection has a copy of the Patient Information Leaflet and the Client's Guide to Prenoxad Injection

5. Dispensing Prenoxad Injection

When dispensing Prenoxad Injection you should not remove the cellophane wrapper. This is because the pack must remain intact to prevent confiscation.

When attaching the patient label it is important that you do not cover any product information or place the label anywhere that could restrict the opening of the pack.

6. List of additional resources

The following additional guides have been developed:

- Client's Guide to Prenoxad Injection (naloxone hydrochloride 1mg/1ml solution for injection)
- Prescriber's Guide to 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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