PACKAGE LEAFLET: INFORMATION FOR THE USER D05171

Prenoxad™ 1mg/ml Solution for Injection in a pre-filled syringe

(naloxone hydrochloride)

Because of your condition it may not be possible for you to read this leaflet before you are given Prenoxad Injection. The leaflet has been provided to you to give some information that you should have and to assist the person who is helping you.

Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Prenoxad Injection contains the medicine naloxone. Naloxone belongs to a group of medicines that reverse the action of opioid drugs e.g. morphine.
This medicine is used to:
- reverse the action of opioid drugs e.g. if you have been given or taken an overdose of these drugs.
- if you are at risk of an opioid overdose you should always carry your Prenoxad Injection with you. It is designed as an emergency rescue treatment but you should still get medical attention as soon as possible.

Prenoxad is used in adults and adolescents 16 years or over.

2. What you need to know before Prenoxad Injection is administered to you

This medicine is often used in circumstances where it is necessary to act very rapidly. You should not be injected with this medicine unless it is in the circumstances that were explained when you were given the Prenoxad Injection.
Prenoxad Injection will only be made available once the prescriber has assessed the suitability and ability of a client or a representative to administer naloxone in the appropriate circumstances.

You should not be given Prenoxad Injection if:
- you are allergic to naloxone or to any other ingredients of this medicine (listed in section 6).

Warnings and precautions
Before giving you Prenoxad Injection your ***prescribing doctor*** as per local clinical guidance ***and the*** trained individual will have undergone training to use Prenoxad Injection and may have considered whether special care needs to be taken if:
- you have taken or been given a large dose of opioid drugs or if you have a drug-dependence (drug addiction) problem
- you have kidney or liver problems
- you have heart or circulation problems
- Prenoxad is not effective in product overdoses other than opioids
- you suffer from high blood pressure, irregular heart beat or difficulty in breathing suffer from high blood pressure, irregular heart beat or difficulty in breathing.

If you have any of these problems you should make your doctor or trained individual aware.

Other medicines and Prenoxad Injection
If you are able, you must tell your doctor or the trained individual administering Prenoxad Injection if you are taking or have recently taken any medicines, including those obtained without a prescription.

Pregnancy and breast-feeding
A number of medicines can interact with Naloxone Injection which can significantly alter their effects. In particular, tell your doctor if you are taking
- Strong pain killer medicines like buprenorphine and pentazocine.
- Sleeping pills
- Medicines that may affect your heart or blood circulation (e.g. antihypertensive drugs, cocaine, methamphetamine, cyclic antidepressants, calcium channel blockers, betablockers, digoxin and clonidine) even those not prescribed.

Prenoxad Injection should not be used if you are pregnant or breast-feeding unless it is absolutely essential.
The potential risk for humans is unknown.

IF THE PATIENT IS BREATHING NORMALLY BUT IS UNROUSABLE OR UNCONSCIOUS:

1. Move the patient into the recovery position, lying on their side, mouth open and pointing towards the ground.
2. Give one dose (0.4 ml) of Prenoxad (to first black line) into the outer thigh or upper arm muscle (through clothing if necessary). Leave the needle attached to the syringe and place on the retaining cradle in box.
3. **Call 999** and ask for an ambulance.
4. Give further intramuscular injections of 0.4ml Prenoxad Injection (to next black line) into the outer thigh or upper arm muscle (through clothing if necessary) every 2–3 minutes using the same needle until the ambulance arrives or the patient regains consciousness.

IF THE PATIENT DOES NOT APPEAR TO BE BREATHING NORMALLY:

1. **Call 999 immediately** and ask for an ambulance.
2. Give basic life support by giving the patient 30 chest compressions and 2 rescue breaths if possible.
3. Give one dose (0.4 ml) of Prenoxad (to first or next black line) into the outer thigh or upper arm muscle (through clothing if necessary) if the patient is still not breathing. Leave the needle attached to the syringe and place on the retaining cradle in box
4. Give 3 cycles of 30 chest compressions and 2 rescue breaths if the patient is still not breathing.
5. Repeat steps 3 and 4 until the ambulance arrives or the patient is breathing normally.

When the patient is breathing normally or has gained consciousness move them to the recovery position (lying on their side, mouth open and pointing towards the ground). Watch continuously.

Breast-feeding should be avoided in the first 24 hours after treatment with Prenoxad Injection.
Naloxone Hydrochloride Injection must be used with caution in breast feeding mothers.

Driving and using machines
This medicine can affect your ability to drive and operate machinery. Do not drive, operate machinery or engage in other activities demanding physical or mental exertion for at least 24 hours if you feel drowsy or cannot think clearly.

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially 'sodium- free'.

3. How Prenoxad Injection will be given

You or the trained person will give one dose (0.4ml) of the injection solution at any one time, into the outer thigh muscle or upper arm muscle (intramuscularly). The number of times injections of 0.4ml will be repeated will depend on your individual need and response to the treatment. The syringe contains in total 5 doses of 0.4 ml.

The pack contains two needles. The second needle is provided in case the first needle is damaged or gets contaminated because for example you have dropped it on the floor.

Adults and adolescents aged 16 years or over

Known or suspected opioid overdose:
Prenoxad Injection should only be given where it is known or suspected that an opioid overdose has occurred.

The following procedure should be followed:

See overleaf for diagrams to help the person give the injections.

If medical assistance has not arrived after you have used up the contents of one syringe and you have a second syringe available then this may be used using the same procedure as with the first. Use of the second syringe in the same way as the first does not present a safety hazard.

Prenoxad Injection is for single patient use only and any unused injection solution should be discarded as instructed in section 5.

Use in children and neonates
This product must not be used by children ***under the age of 16 years*** and neonates in the home or non-medical setting.
If your child is given or has taken an opioid overdose, you should call an ambulance straight away and start giving chest compressions with rescue breaths if necessary.

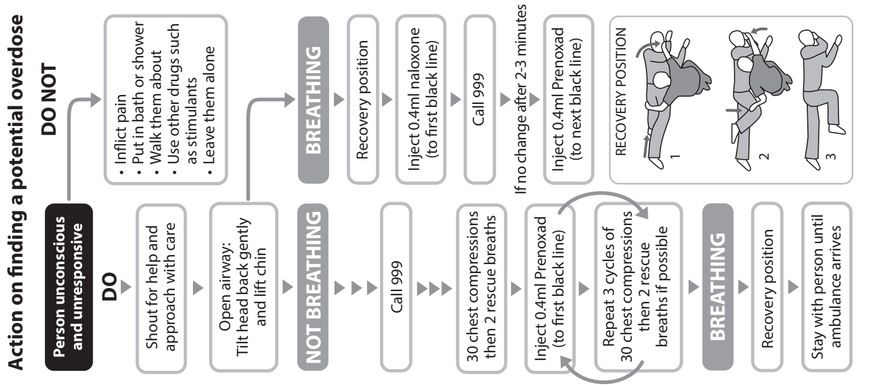
If you are given more or less Prenoxad Injection than you should have
If you think you have been given too much or too little tell your doctor or the ambulance crew at the scene of the overdose. The following symptoms have been observed if too much Prenoxad has been given:
Seizure, decrease or increase blood pressure, decrease heart rate and memory impairment.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Other side effects may include:
Very common (may affect more than 1 in 10 people): feeling sick.
Common (may affect up to 1 in 10 people): dizziness, headache, faster beating of the heart, decreased or increased blood pressure, vomiting or pain.
Uncommon (may affect up to 1 in 100 people): tremor, sweating, over breathing (hyperventilation), irregular heartbeat, decreased heart rate, diarrhoea, dry mouth, local irritation, inflammation, faster or deeper breathing.
Rare (may affect up to 1 in 1,000 people): fits (seizure), tension.
Very rare (may affect up to 1 in 10,000 people): Severe problems with the heart (Fibrillation and cardiac arrest),fluid in the lungs,discolouration and lesions of the skin,allergic reactions (urticaria, rhinitis, dyspnoea, Quincke's oedema), anaphylactic shock.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.



5. How to store Prenoxad Injection

Keep this medicine out of the sight and reach of children.
The expiry date refers to the last day of that month.

You should not be given Prenoxad Injection after the expiry date which is printed on the box and syringe label. The doctor, nurse, pharmacist or trained individual administering Prenoxad Injection will check the expiry date on the box and syringe label before giving the pack to you.

Do not throw away any medicines via wastewater or household waste. Ask your doctor, pharmacist, or nurse how to throw away medicines including used and unused needles you no longer use. Following use, any left over product, including used and unused needles, may be given to the attending ambulance crew. These measures will help protect the environment.

Store in the original container.
This medicine does not require any special temperature storage conditions. Keep the syringe in the plastic box in order to protect from light.
If the injection is discoloured it should not be used.

6. Contents of the Pack and other information

What Prenoxad Injection contains.
The active substance is Naloxone Hydrochloride 1mg per ml.
The other ingredients are Sodium Chloride, Water for Injection and Dilute Hydrochloric Acid.

What Prenoxad Injection looks like and contents of the pack.
The injection is supplied in a 2ml prefilled syringe containing 2ml of a clear, colourless solution together with two needles. The syringe and needles are contained in a yellow box.

Marketing Authorisation Holder:
Aurum Pharmaceuticals Ltd
Bampton Road
Harold Hill
Romford, RM3 8UG
United Kingdom

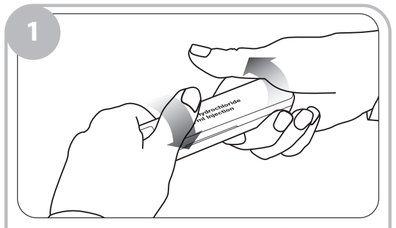
Manufacturer:
Macarthys Laboratories Ltd
T/A Martindale Pharma
Bampton Road, Harold Hill
Romford, RM3 8UG
United Kingdom

Product Licence Number: PL 12064/0125
Date of last revision: June 2021

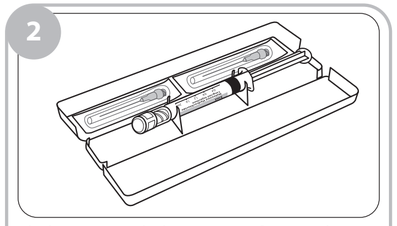
Instructions for administration to patients may be found below

MARTINDALE PHARMA
Bampton Road Harold Hill Romford RM3 8UG UK

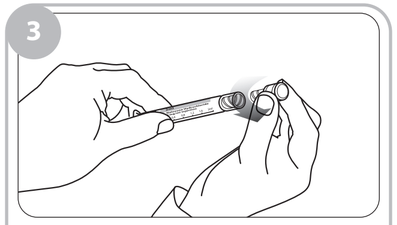
Instructions for patient administration



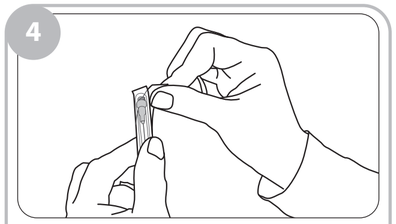
1. Remove the clear film wrapping by pulling the tear strip on the side of the box. Twist the outer plastic box as shown to break the tamper evident seals and open.



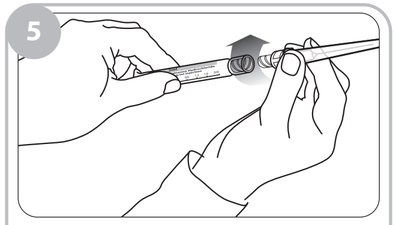
2. The box contains the kit: 1 syringe of Prenoxad, two needles and a Patient Information Leaflet. The syringe sits securely inside a retaining cradle.



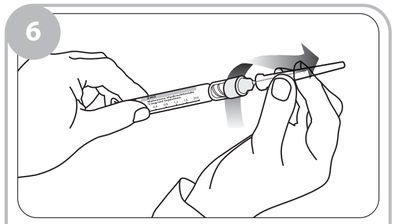
3. Unscrew the clear plastic top from the syringe.



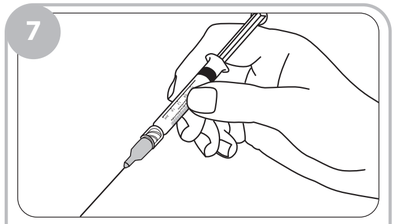
4. Peel back the backing paper from the needle packet and remove the needle in its protective sheath.



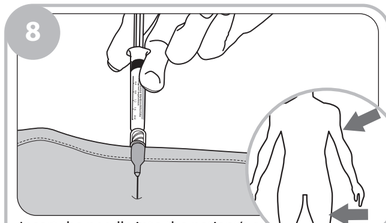
5. With the needle still in its sheath, screw the blue fitting on to the syringe.



6. Gently twist the needle sheath and remove it from the syringe.



7. To inject someone who has overdosed, hold the syringe like a pen.



8. Insert the needle into the patient's outer upper arm muscle, through clothing if necessary, and inject first dose (0.4ml) to the first black line.

Withdraw the needle and syringe after each dose and return the syringe to the retaining cradle within the Prenoxad box, leaving the needle attached. Do not re-sheath the needle. If you need to give another dose, insert the same needle again into the patient and inject to the next black line.

9. The extra needle contained in the Prenoxad box is included as a safety precaution in case the first needle breaks.

10. After you or a trained person has used Prenoxad injection (as described in section 3. How Prenoxad is given), 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 can dispose of the used Prenoxad Injection pack by handing it into a pharmacy or any needle exchange service.

Discard any unused solution immediately after use.
Prenoxad Injection should not be disposed of via drainage or household waste.

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