Issuer's Guide

Prenoxad®Injection

(naloxone hydrocholoride 1mg/ml solution for injection)

For more information go to www.prenoxadinjection.com

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Introduction

Please review this document carefully before issuing Prenoxad® Injection.

Prenoxad® Injection is a licensed 'take home' naloxone product 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 a community setting can play a significant role in the prevention of accidental opioid related overdose death for people who use illicit or prescribed opioids.

Prenoxad® Injection contains naloxone hydrochloride 1mg/ml solution for injection in a 2ml pre filled syringe

Contents

1. Purpose of the Issuer's Guide

This document is intended to be used by people working in drug treatment services or other services that are involved in the delivery of training and supply of Prenoxad® Injection. Please refer to your organisational policies / procedures, and to the national and local guidance in your services regarding staff/volunteers who may issue Prenoxad® Injection.

For information about existing UK legislation and Public Health England guidance that supports the supply of naloxone, please visit;

www.gov.uk/government/publications/widening-the-availability-of-naloxone/widening-the-availability-of-naloxone

For information and guidance about training and supply in Scotland, please visit;

www.sdf.org.uk/what-we-do/reducing-harm/take-home-naloxone/

The marketing of Prenoxad® Injection is the subject of additional risk minimisation measures that support the proper use and supply of this medicine. Various documents are available and we encourage you to take the time to read these. These can be found or requested from **www.prenoxadinjection.com**.

This document does not replace the Summary of Characteristics (SmPC), and only seeks to supplement it. Please read this issuers guide in conjuction with the following documents, and information/training videos found on the product website.

- **Prenoxad® Injection SmPC**
- **Prenoxad® Injection Client Guide**
- **Prenoxad® Injection Training Manual**
- **Prenoxad® Injection website (www.prenoxadinjection.com)**

2. Role of the Client's Guide

The Client's Guide is designed for people who have been issued a Prenoxad® Injection kit.

The objectives of the Client's Guide are to serve as a reminder about the training that would have been given to either the client and/or representative on the following topics:

- **How to identify an overdose**
- **How to assemble and give Prenoxad® Injection**
- **How to put someone in the recovery position**
- **How to perform CPR**
- **How to give rescue breaths**
- **Remind about the importance of calling for help**
- **How to get resupply**

3. Role of the Training Manual

The Training Manual is there to support people who deliver the Prenoxad® Injection training to clients, their representatives and others. It should be used along with the 'how to' training videos, found on **www.prenoxadinjection.com**. The objectives of the Training Manual are to assist the trainer in delivering the following key messages to either a client or their representative before a Prenoxad® Injection kit is issued:

- **What Prenoxad® Injection is and what it is used for**
- **How a client or their representative can be issued with a Prenoxad® Injection kit**
- **When to use Prenoxad® Injection**
- **How to assemble and inject Prenoxad® Injection**
- **How to dispose of Prenoxad® Injection**
- **How to perform CPR**
- **How to give rescue breaths**

4. What to consider before Issuing Prenoxad® Injection

Before issuing Prenoxad® Injection, ensure that you are familiar with the Prenoxad® Injection SmPC (available at https://www.medicines.org.uk/emc/product/3054/smpc).

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.

If you do not deliver the training elements yourself, but are responsible for issuing kits to people (for example as resupply after initial training was completed elsewhere), you can use the 'Individual Training Checklist' to briefly review and correct any knowledge gaps with the client before issuing a kit. This Checklist can be found at the back of the training manual.

If needed please talk through the Client's Guide to Prenoxad® Injection with clients and their representative and make sure they take a copy with them.

Other actions to consider before Prenoxad® Injection is issued:

It's important to be sure that anyone supplied with Prenoxad® Injection is competent and confident to use it.

However it is also VITAL that people supplied with Prenoxad® Injection fully understand the short acting nature of naloxone, and therefore the importance of calling 999 immediately upon the discovery of a suspected overdose.

Before issuing Prenoxad® Injection, check and confirm that the client or representative has been given instructions on;

- **How to recognise the signs/symptoms of overdose**
- **How to safely assess a casualty**
- **How to call 999/knows what to expect if they have to call 999**
- **How to move someone into the recovery position/perform CPR**
- **How to assemble and how to administer the correct dose(s) of Prenoxad® Injection**

Check that the person being issued with a Prenoxad® Injection kit;

- **Is familiar with the Client's Guide to Prenoxad® Injection and takes a copy with them**
- **Is aware of what may happen after administration and understand the need for immediate medical assistance**
- **Understands the need to inform their representative, family and/or friends of when and how to use Prenoxad® Injection and where it can be found**
- **Understands how to correctly dispose of Prenoxad® Injection**
- **Is familiar with the Patient Information Leaflet**

Points 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.

5. What are the risks with Prenoxad® Injection

Like any medicine, Prenoxad® Injection can cause side effects. It's very important to discuss these with the client or representative who is being issued with a kit. Full details of all adverse effect can be found in section 4.8 of the current SmPC **(https://www.medicines.org.uk/emc/product/3054/smpc).**

As part of the risk minimisation measures special emphasis is placed on the following types of adverse effects:

- **Recurrence of respiratory depression**
  Symptoms may include shortness of breath, slow or shallow breathing, bluish tinge to lips and finger nails, and disorientation.
- **Precipitation of opioid withdrawal syndrome**
  Symptoms may include watery eyes, runny nose, sweating, cramps, vomiting, chills, shakiness, restlessness, and gooseflesh skin.
- **Cardiovascular effects**
  Symptoms may include feeling like your heart is beating too fast or out of your chest, chest pain and pain in arm(s) or jaw.
- **Hypersensitivity**
  Symptoms may include redness, itching, swelling, rash, wheezing, cough, sneezing and shortness of breath.
- **Limited efficacy**

Clients and their representatives should be encouraged to report any possible side effects that they notice to the issuing drug service. The issuing drug service is encouraged to report these possible side effects:
In the UK these can be reported either via the yellow card scheme to the MHRA.
www.mhra.gov.uk/yellowcard

or directly to the company
drugsafety.uk@ethypharm.com

6. Additional Resources

These are available on the Prenoxad® Injection website (**www.prenoxadinjection.com**).
This material can also be requested from Ethypharm's Medical Information Department: **medinfo@ethypharm.com**.