Prenoxad (naloxone hydrochloride) 1mg/ml Solution for Injection in a prefilled syringe
Prescribing Information
Please refer to the Summary of Product Characteristics (SPC) 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, 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 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 and the Elderly: 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. Consult SPC for further information. **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. 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 SPC for further information. **Interactions:** Prenoxad Injection should be administered cautiously to persons including new-borns of mothers who are known or suspected to be physically dependent on opioids. In such cases an abrupt and complete reversal of narcotic effects may precipitate an acute abstinence syndrome. **Pregnancy and Lactation:** The safety of this medicinal product for use in human pregnancy has not been established, therefore, Prenoxad should be used with caution in pregnancy. 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. Naloxone may be administered to mothers during the second stage of labour to correct any respiratory depression due to opioid analgesics. It is not known if Naloxone affects the duration of labour and/or delivery. It is not known whether Naloxone is excreted in human milk, therefore use with caution in breastfeeding mothers. **Effects on ability to drive and use machines:** Not Applicable. **Undesirable Effects:** Very common side effects include nausea. Common side effects include: vomiting, dizziness, headache, ventricular tachycardia, hypotension and hypertension and postoperative pain. Uncommon side effects include: tremor, sweating, arrhythmia, bradycardia, diarrhoea, dry mouth, hyperventilation, irritation of vessel wall (after i.v. administration); local irritation and inflammation (after i.m. administration); higher than recommended dosage in postoperative use can lead to the return of pain; a fast reversal of opioid effect can induce hyperventilation. Other side effects include: seizures, tension, allergic reactions (urticaria, rhinitis, dyspnoea, Quincke's oedema), anaphylactic shock, fibrillation, cardiac arrest, pulmonary oedema when used in postoperative patients, erythema multiforme, fever, nervousness, restlessness, irritability, dyspnoea, runny nose, sneezing, yawning, piloerection, weakness, shivering; death when used in postoperative patients or when reversal of opioid depression is abrupt, Increased blood pressure when reversal of opioid depression is abrupt; agitation when administered in excessive doses to postoperative patients; reversal of analgesia when administered in excessive doses to postoperative patients. Consult SPC for further information. **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 266600. **Date of Preparation:** May 2018.

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