Anyone with Prenoxad (naloxone) injection kits must check for missing needles

A small number of kits of Prenoxad (naloxone) 1mg/ml Solution for Injection in a pre-filled syringe, an emergency medicine for suspected opioid overdose, may be missing needles, which would mean that some individuals may not be able to administer life-saving doses of this medicine in an emergency.

The Medicines and Healthcare products Regulatory Agency (MHRA) is urging patients, carers and healthcare professionals who have kits of Prenoxad Injection for emergency situations to visually check the contents of their kits by holding the front of the sealed kit against a light source to confirm that there are two (2) needles inside their kit. If the kit does not have two needles, it should be returned and replaced. Detailed instructions and reference images on how to visually check the kits can be found in the MHRA patient letter.

If it is not possible to confirm the presence of two needle packets visually, holders of Prenoxad Injection can open their kits without touching the pre-filled syringe (the tube with liquid in) to confirm there are two needles inside each kit. Once the check is completed, the kit must be carefully closed to ensure the contents stay secure. People can ask a healthcare professional if they are not sure how to visually check or physically open a Prenoxad Injection kit.

Healthcare professionals, services providers and local teams, including those involved in needle exchange services, have been asked by the MHRA to contact people who have been supplied Prenoxad Injection kits to ask them to check their kits for missing needles, and to arrange a replacement if needed.

This issue was detected when the manufacturer received reports from France of missing needles in kits of Prenoxad Injection. These kits normally contain 2 needles along with the pre-filled syringe containing the active ingredient (naloxone) and the Patient Information Leaflet. Although there are no reports to date of kits in the UK with missing needles, the potential for a small number of kits to have fewer than two (2) needles cannot be ruled out. There is no evidence to date that this manufacturing error has caused any harm to patients in the UK.

Dr Alison Cave, MHRA Chief Safety Officer, said:

> Patient safety is always our priority. It is vitally important that you visually check the contents of your Prenoxad Injection kit and if there are fewer than two needles, you should return your kit and obtain a replacement. If you have been given a kit of this medicine since 27 March 2020 and are unsure how many needles it contains,

please seek advice from the healthcare professional or service provider who supplied this kit.

If needed, your healthcare professional or service provider will give you a replacement kit or refer you to their nearest supplier. This will usually be a drug treatment service, a community pharmacy, a needle and syringe programme, a peer support group, or a drugs outreach worker.

We have taken prompt action to ensure kits with missing needles will no longer be given to patients. There are no concerns about the medicine in these kits and other products containing naloxone have not been affected by this manufacturing error. Please report any issues with your Prenoxad Injection kit via the Yellow Card scheme website.

Prenoxad Injection is carried by people at risk of opioid overdose, or those who know people at risk of overdose. It is used during emergencies at home, in non-medical spaces or in healthcare facilities for the complete or partial reversal of respiratory depression caused by natural and synthetic opioids including methadone, and some other opioids such as dextropropoxyphene and certain mixed analgesics: nalbuphine and pentazocine. Prenoxad Injection may also be used for the diagnosis of suspected severe opioid overdose.

Further information

- Detailed instructions and reference images on how to check Prenoxad Injection kits for missing needles are included in the MHRA patient letter.

- Anyone experiencing or observing someone experiencing symptoms of opioid overdose should immediately seek medical assistance. If there is nasal naloxone or injectable naloxone (with a needle) available, it should be administered according to the instructions in the kit. If someone has symptoms of an opioid overdose and is not breathing, 999 should be called and an ambulance requested immediately. General symptoms of opioid overdose include pinpoint pupils, loss of consciousness, respiratory depression (breathing slows or stops), extremely pale face that may feel clammy to the touch, bluish purple tinge to lips or fingernails, no response to noise, cannot be awakened, unable to speak, vomiting and/or making gurgling noises.

Notes to editors

- National Patient Safety Alert: Class 4 Medicines Defect Information: Prenoxad 1mg/ml Solution for Injection – This is a Caution in Use (Class 4) notification involving all batches on the UK market of Prenoxad 1mg/ml Solution for Injection in a pre-filled syringe: approximately

466,700 kits.

- Detailed instructions for healthcare professionals can be found in the notification.

- The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. MHRA is an executive agency, sponsored by the Department of Health and Social Care.