25th Nov 2022

PRODUCT DEFECT ALERT

TGA Recall Action Reference Number: RC-2022-RN-01457-1

PRENOXAD 1mg/mL Solution for Injection in a pre-filled syringe (naloxone hydrochloride) Section 19A medicine

To Whom it May Concern,

Phebra Pty Ltd, following consultation with the Therapeutic Goods Administration (TGA), wish to inform you of the potential that a small number of PRENOXAD 1mg/mL pre-filled syringe kits could be missing one or both needles within the product kit.

The following batches are potentially affected by this product defect alert:

Batch number	Expiry date
0141035	06/2025
0138904	01/2025
0130203	08/2023
0126941	05/2023
0120140	02/2023

Information for Health Care Professionals

The product manufacturer has notified Phebra Pty Ltd that a limited number of Prenoxad kits (also called packs) in a batch marketed in France have missing needles.

Although no reports of Australian kits with missing needles have been received to date, the potential for kits to contain fewer than two (2) needles in all distributed batches in Australia (listed above) cannot be excluded based on the investigation by the manufacturer. However, due to the critical need for this product to be available, the specified batches are **not** being recalled.

Prenoxad kits are packed with two (2) Terumo 23-gauge 1¼ inch needles, along with the pre-filled syringe containing the active ingredient naloxone hydrochloride, and a Patient Information Leaflet.

Naloxone is a drug that reverses the effects of an opioid overdose. If no needles are present at the time of administration, there is a risk that patients, members of the public and/or healthcare professionals may not be able to administer life-saving doses of naloxone from these kits in an emergency. This may impede the treatment for a patient with an opioid overdose, which may result in delay to intervention and possible death.

Healthcare professionals and service providers should note the guidance below before supplying Prenoxad kits.

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Advice for all healthcare professionals and service providers, including community pharmacies and emergency services,

- Check all Prenoxad kits in place at your organisation against the batches specified in this notification.
- Confirm two (2) needle packets are present in the kit, hold the front of the kit (with the Lot number and 2D matrix facing you) and visually inspect against a light source (see images in Appendix 1).
- If needles cannot be clearly seen with the visual inspection of the kits, the kits can be physically opened to confirm the presence of two (2) needles inside (see images in Appendix 2). The kits can be closed after visual inspection.

  As the tamper evident seal (TES) will be broken as part of the physical inspection process, it is recommended that a copy of this letter be available for sighting or provision in the event of patient/individual/member of the public concern around the broken seal. **Note that the clear plastic cap at the end of the pre-filled syringe must remain intact in order to maintain sterility of the medicinal product (see image in Appendix 3). Click the kit close after it is opened to ensure the contents stay secure.**
- **Where there are kit(s) in your stock without two (2) needles, quarantine these immediately and contact Phebra to arrange for replacement kit(s). Similarly, where there are concerns around visual or physical inspection of the kit(s), healthcare professionals, service providers and local teams should contact Phebra for further advice or to arrange replacement kit(s). Contact Phebra by e-mail at orders@phebra.com or by phone on 1800 720 020 and ask to speak to Customer Services.**
- If use is required in an emergency, and needles are missing from the kit, Terumo 23 gauge 1¼ inch needles or reasonable alternative needles should be used for intramuscular administration of Prenoxad.

Where healthcare professionals, service providers and local teams (including those involved in needle and syringe programmes) are able to make contact with patients and members of the public who have been supplied with Prenoxad, they should inform them to check their kits to ensure they contain two (2) needles in each kit. Support should be provided to individuals with kits who are unsure how to check their kits. The action to contact all holders of kits will depend on the local procedures for record keeping, but efforts should be made to inform all likely holders of Prenoxad.

- If patients, individuals or members of the public report a Prenoxad kit **without** two (2) needles in the kit, arrange for a replacement and visually check for the presence of two needles before supplying the new Prenoxad kit, as per the instructions in the appendices.
- Report any defective kits to Phebra Pty Ltd including if kits are found to have fewer than two (2) needles in the kit. Include the batch number in any reports to Phebra. **Contact Phebra by e-mail at orders@phebra.com or by phone on 1800 720 020 and ask to speak to Customer Services.**

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Advice for patients and members of the public, including peers, friends, family, carers

- Check to see if you have any kits of Prenoxad Injection in your possession or at home. It is possible that some Prenoxad kits contain fewer than two (2) needles in each kit. A needle is needed to administer the medicine (naloxone) from the pre-filled syringe. If a needle is not available, this means the medicine cannot be used to reverse opioid overdose in an emergency.
- Anyone with a Prenoxad kit is asked to visually check the contents by holding it against a light source to confirm the presence of two (2) needle packets. See images in Appendix 1 for reference.
- Alternatively, you could open your Prenoxad Injection kit to confirm that there are two (2) needles in each kit. See images in Appendix 2 for reference. If you open the kit, do not touch the pre-filled syringe (the tube with liquid in). The clear plastic cap at the end of the pre-filled syringe must be intact so that the injection remains sterile. See images in Appendix 3 for reference. The kits can be closed after visual inspection. Always click the kit closed after it is opened to ensure the contents stay secure.
- If you are unclear on how to visually check or physically open a Prenoxad kit, you can take it back to the healthcare professional or service provider who initially supplied this medicine to you and request assistance in checking the kit. This may be the local drug treatment service, a community pharmacy involved in support programmes, needle and syringe programmes, peer support groups, or drugs outreach workers.
- If you see that your kit does not contain two (2) needles, you must take it back to the provider who gave you the kit, or a community pharmacy involved in needle and syringe programmes, or a local substance misuse team or service provider, for a replacement.
- As per the advice stated in the Patient Information Leaflet Prenoxad Injection should be carried by people at risk of an opioid overdose, therefore it is important that you have a replacement provided to you when you return any affected kits.
- There are no concerns about the medicine in these kits. If you, or somebody you observe, has taken an opioid and are experiencing the symptoms of opioid overdose, please seek medical assistance or visit the nearest accident and emergency centre. If you have nasal naloxone or injectable naloxone (with a needle) available, administer it according to the instructions in the kit. Symptoms of overdose can include the following:
  - pinpoint pupils
  - loss of consciousness (i.e. the person cannot be woken)
  - 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 or making gurgling noises
- Refer to the Patient Information Leaflet for further information.

If someone has symptoms of an opioid overdose and is not breathing, call 000 and ask for an ambulance immediately.

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Thank you for your assistance in helping us manage this product defect alert.

Yours sincerely,

Dr. Michael Crothers

Chief Quality and Scientific Officer

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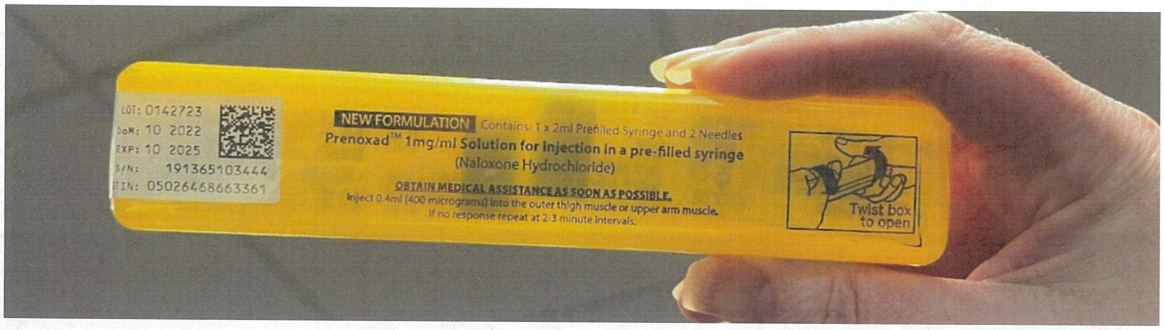
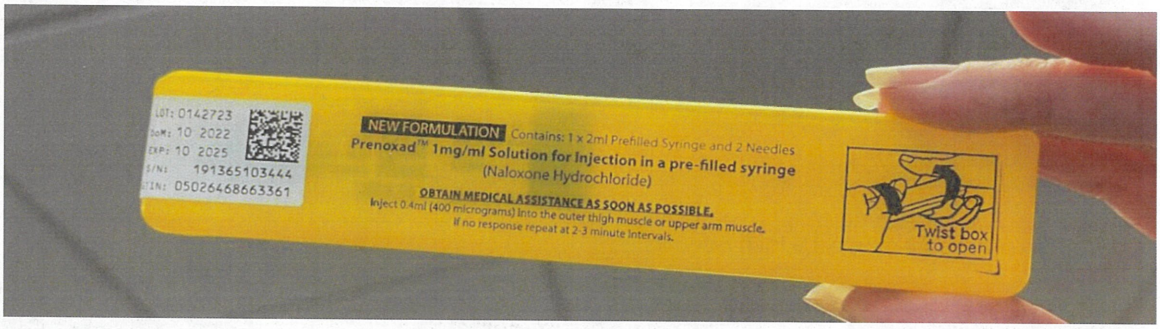
Appendix 1: Images of Prenoxad kits containing two (2) needle packets which can be visually checked against a light source.

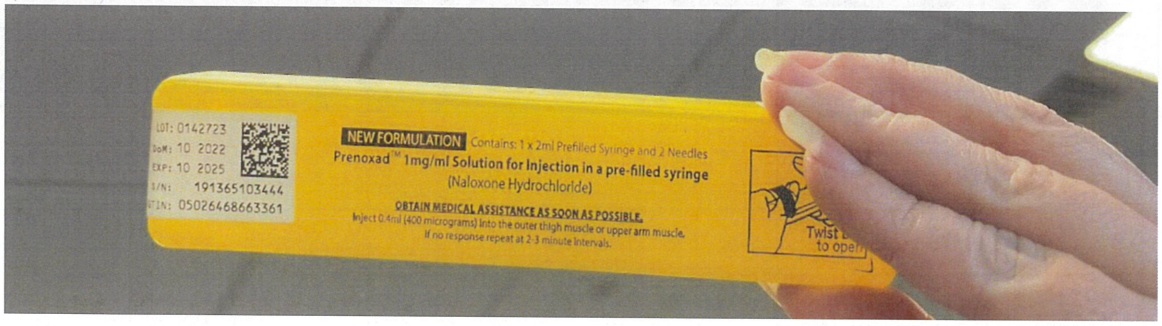
If needles are present, two (2) dark squares can be seen in the middle of the kit, off set slightly as shown below:



If one (1) needle is present, only one (1) dark square will be seen as shown below:



If no needles are present, the dark squares cannot be seen as shown below:



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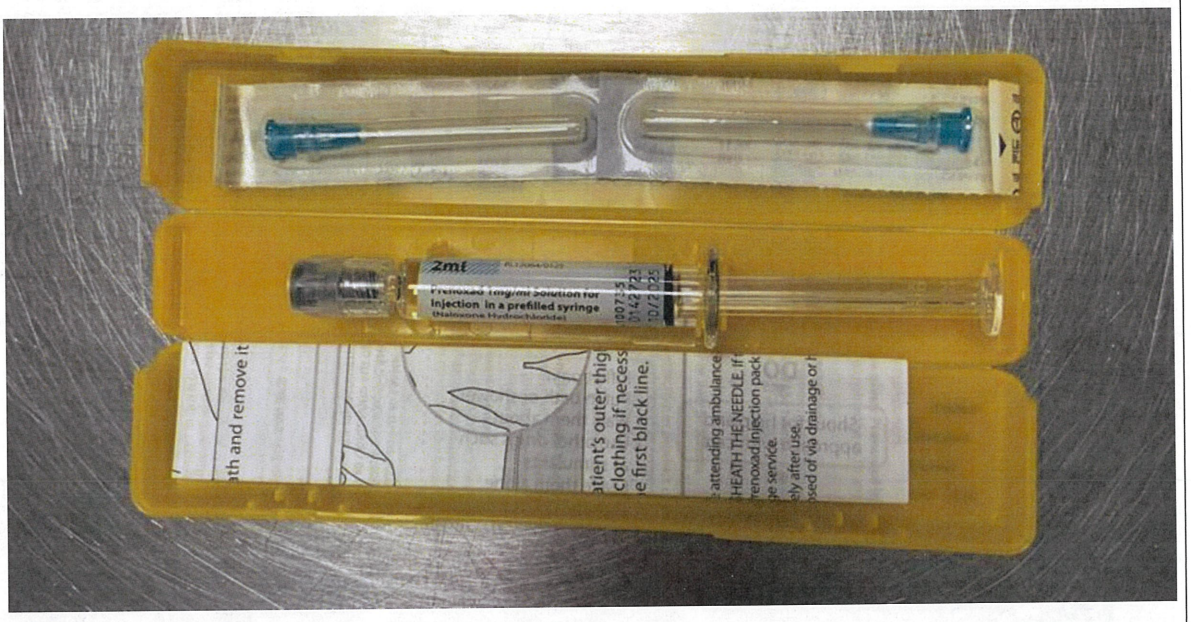
Appendix 2: Contents of an opened Prenoxad kit, and images of Terumo 23 gauge 1¼ inch needles

Contents of an opened kit. Prenoxad kits are packed with two (2) Terumo 23 gauge 1¼ inch needles, along with the pre-filled syringe containing the active ingredient (naloxone hydrochloride), and a Patient Information Leaflet



Two (2) Terumo 23 gauge 1¼ inch needles

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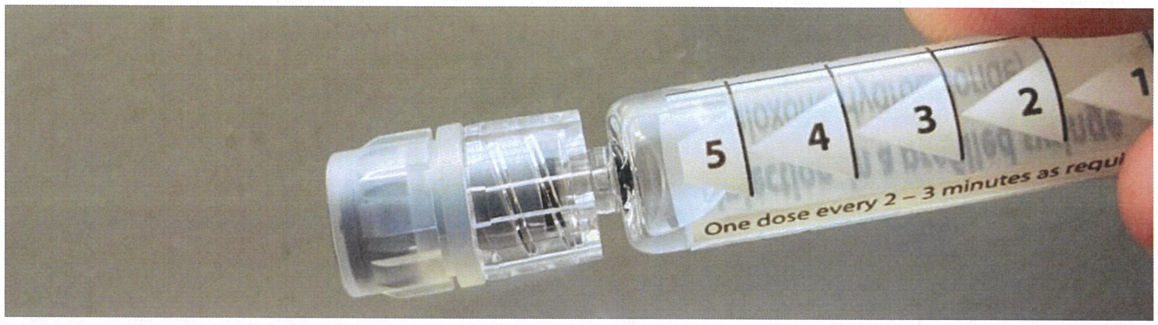
Appendix 3: Image of the clear plastic cap at the end of the pre-filled syringe that needs to remain intact

Image detailing the clear plastic cap at the end of the pre-filled syringe that must remain intact in order to maintain sterility of the medicinal product



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