Medicines & Healthcare products Regulatory Agency

Class 4 Caution In Use Medicines Notification; Supplementary information: Prenoxad 1mg/ml Solution for Injection in a pre-filled syringe (NatPSA/2022/009/MHRA)

Information for confirmed or potential holders of Prenoxad kits

Summary

- A manufacturing problem may mean your Prenoxad kit is missing the correct number of needles – this could prevent you from using it in an emergency
- Follow the instructions to check for missing needles in any Prenoxad kits you hold
- If you are not sure how to check the number of needles, ask a healthcare professional or service provider for advice
- If a needle is missing (each kit should contain two (2) needle packets), take it back to the person who gave you the kit or to another healthcare setting for a replacement
- There are no concerns about the naloxone medicine in the kit – you should continue to use your kit in situations of opioid overdose if a needle is present

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe.

We have been told by the manufacturer of Prenoxad (naloxone) that some packs (also called kits) may not contain the correct number of needles.

Prenoxad Injection contains naloxone. Naloxone reverses the effects of an opioid overdose. Prenoxad Injection kits include:

- two (2) needles for injecting naloxone into muscle
- a pre-filled syringe containing naloxone hydrochloride liquid
- instructions in the Patient Information Leaflet

If no needles are in the kit when you need to use it, you may not be able to administer life-saving doses of naloxone. This may delay the treatment for someone with an opioid overdose and may prevent you from saving their life – so it's very important you check your kits as soon as possible.

Although we have not seen any reports of UK kits with missing needles, we cannot exclude that some kits supplied to people in the UK have fewer than two (2) needles. We expect that only a small number of kits are affected. Due to the critical need for this product to be available, we are not recalling these kits. As a precautionary measure, we ask people to take the steps listed on page 2.

Steps to take to check Prenoxad Injection kits

1. Check to see if you have any kits of Prenoxad Injection in your possession or at home.

2. Visually check the contents – hold the kit up to a light source to see if you can confirm there is two (2) needle packets in the kit. See images in Appendix 1 for reference.

3. Alternatively, you can open your Prenoxad kit to confirm that there are two (2) needles in each kit. See images in Appendix 2 for reference. If you do this, do not touch the pre-filled syringe (the tube with liquid in). The clear plastic cap at the end of the syringe must be intact so that the injection remains sterile and free from contamination. 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.

4. If you are unclear on how to visually check or physically open a Prenoxad kit, take it back to a healthcare professional or the 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) needle packets, you must take it back to the provider who gave you the kit for a replacement. You can also take it to a community pharmacy (involved in needle syringe programmes) or a local substance misuse team or service provider for a replacement.

As per the Patient Information Leaflet, Prenoxad kits 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 impacted kits. Prenoxad kits can also be supplied to the friends, family or other representative of someone identified to be at risk of opioid or opioid-related overdose, and to anyone likely to witness an overdose.

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 listed below, 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 opioid overdose

- 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

If someone has symptoms of an opioid overdose and is not breathing, call 999 and ask for an ambulance immediately.

Please see Patient Information Leaflet for further information.

The company and MHRA have not received any product complaints or adverse reactions related to this issue. Adverse reactions should also be reported via the MHRA Yellow Card scheme.

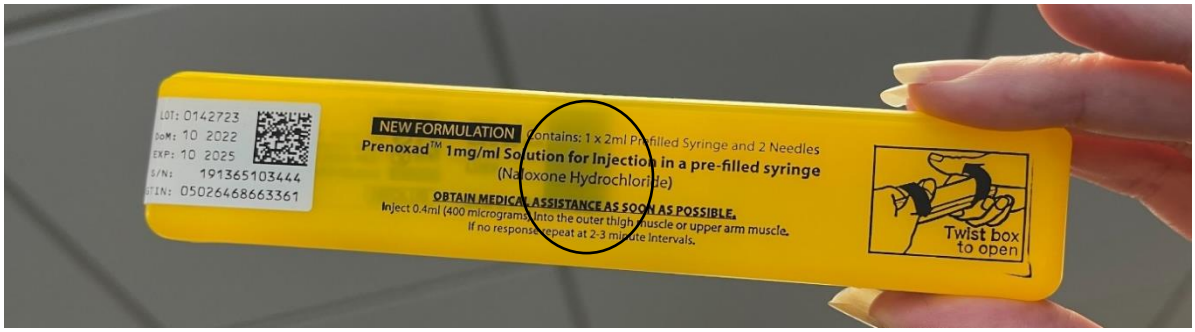
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Appendix 1: Images of Prenoxad kits containing two (2) needle packets which can be visually checked against a light source

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



If one (1) needle is present, only one (1) dark square will be seen as shown below and indicated by the circle below on the image:



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



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



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

