National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

Prenoxad 1mg/ml Solution for Injection in a pre-filled syringe, Macarthys Laboratories, (Aurum Pharmaceuticals Ltd), caution due to potential missing needles in sealed kits

Date of Issue:	10-Nov-22	**Reference No:**	NatPSA/2022/009/MHRA

This alert is for action by: primary and secondary care, specifically those involved in outreach services

This is a safety critical and straightforward National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards) supported by Chief Pharmacists, Chief Nurse and Head of Procurement/Supplies or equivalent roles, as well as leaders in general practice and community pharmacy, in collaboration with Directors of Public Health/Commissioners and providers of drug treatment and prevention services and other relevant service.

DMRC Medicines Defect Classification	Class 4 Medicines Defect Information: Caution In Use

Explanation of identified safety issue:

Macarthys Laboratories (trading as Martindale Pharma, an Ethypharm Group Company), has notified the MHRA that a limited number of Prenoxad kits (packs) in a batch marketed in France have missing needles.

Although no reports of UK marketed kits with missing needles have been received to date, the potential for kits to contain fewer than two (2) needles in all distributed batches (see page 2) cannot be excluded based on the investigation by the company. However, due to the critical need for this product, 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 in the kit, 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 actions required before supplying Prenoxad kits.

We ask providers to contact individuals supplied with Prenoxad kits where possible and support checks to ensure kits contain two (2) needles in each kit. Support should be provided to individuals with kits who are unsure how to check their kits. See page 2 and supplementary information.

Please see the Summary of Product Characteristics for additional information on safety of this product.

Actions required

Enact an action plan to implement actions in the MHRA Class 4 Medicines Defect Information: Caution in Use by 17 November 2022. This includes:

- Check all Prenoxad kits in place at your organisation against the batches specified in this alert.
- Visually inspect the front of the kit (with the Lot number and 2D matrix facing you) against a light source to confirm two (2) needle packets are present in the kit (see images in the MHRA Class 4 Medicines Defect Information).
- If needles cannot be clearly seen by the visual inspection of the kit(s), the kit(s) can be physically opened to confirm the presence of two (2) needles inside the kit(s) (see images in the Medicines Notification). The kit(s) 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 kit(s) are only opened at the point of dispensing or supplying to a patient/member of the public, so that they are aware of the reason for breaking the 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 images in the MHRA Class 4 Medicines Defect Information).
- Where there are kit(s) in your stock without two (2) needles, quarantine these immediately and contact Ethypharm to arrange for replacement kit(s). Similarly, where there are concerns around visual or physical inspection of the kit(s), contact Ethypharm for further advice or to arrange replacement kit(s).
- Report any defective kits via the MHRA Yellow Card scheme, including if kits were without two (2) needles in the kit. Include the batch number in this report.
- If urgent use of Prenoxad 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.
- If patients 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 (2) needles before supplying this.

See further information on page 2 related to advice for contacting patients.

For further detail, resources and supporting materials see: www.gov.uk/drug-device-alerts

Failure to take the actions required under this National Patient Safety Alert may lead to regulatory action

Additional information:

Product Information: Macarthys Laboratories (Marketing Authorisation Holder: Aurum Pharmaceuticals Ltd)

Prenoxad 1mg/ml Solution for Injection in a pre-filled syringe (naloxone hydrochloride) **PL12064/0125**

Batch/Lot Number	Expiry Date	Kit Size	First Distributed
0116917	02/2023	1 kit	27 March 2020
0119973	02/2023	1 kit	09 April 2020
0120140	02/2023	1 kit	09 April 2020
0125553	04/2023	1 kit	13 May 2020
0125555	04/2023	1 kit	24 July 2020
0125724	04/2023	1 kit	09 June 2020
0126941	05/2023	1 kit	03 July 2020
0126943	06/2023	1 kit	16 July 2020
0130203	08/2023	1 kit	06 October 2020
0130732	08/2023	1 kit	16 October 2020
0130843	09/2023	1 kit	15 October 2020
0134251	01/2024	1 kit	26 February 2021
0136031	04/2024	1 kit	01 July 2021
0136536	05/2024	1 kit	03 August 2021
0136551	05/2024	1 kit	03 August 2021
0137656	09/2024	1 kit	24 October 2021
0137768	10/2024	1 kit	07 December 2021
0138525	11/2024	1 kit	26 January 2022
0138904	01/2025	1 kit	14 March 2022
0139907	04/2025	1 kit	17 May 2022
0140236	04/2025	1 kit	10 June 2022
0141035	06/2025	1 kit	22 September 2022
0141812	07/2025	1 kit	21 October 2022
0141969	08/2025	1 kit	11 October 2022

Defective Medicines Report Centre Reference: MDR 219-10/22

Further advice for all healthcare professionals and service providers, including community pharmacies, emergency services and prisons

Where healthcare professionals, service providers and local teams (including those involved in needle and syringe programmes), are able to contact 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. This action will depend on the local procedures for record keeping, but efforts should be made to inform all likely holders of Prenoxad. Please see Supplementary Information provided.

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

It is possible that some Prenoxad kits contain fewer than two (2) needles in each kit. Anyone with a Prenoxad kit is asked to visually check the contents by holding them against a light source to confirm the presence of two (2) needle packets. Detailed instructions are available in the Supplementary Information provided.

Where a kit is found to have fewer than two (2) needles included, this should be taken back to the provider who initially supplied the kit, or to 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 the affected kit. There are no concerns about the medicine in these kits.

If you, or somebody you observe, has taken an opioid and are experiencing the opioid overdose symptoms (see list in the Medicines Notification using the link 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. 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.

For more information on licensed stock and resupply queries for the licensed presentation, please contact licensed@ethypharm.com; or 0800 028 7933. For medical information queries and other enquiries, please contact medinfo@ethypharm.com; or 01277 266 600.

Reference Information:

MHRA Class 4 Medicines Defect Information: Caution In Use (including reference images and Supplementary Information) – Click Here

Defective Medicines Report Centre/ Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU | Telephone +44 (0)20 3080 6574 / DMRC@mhra.gov.uk.

Please check website www.gov.uk/drug-device-alerts for when actions should be ceased or advice to check for date restrictions are lifted.