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IMMEDIATE MESSAGE TO:

- 1. Directors of Pharmacy
- 2. Medical Directors NHS Boards

16 March 2023

Dear Healthcare Professional,

DRUG ALERT CLASS 4 DRUG ALERT 10 2022 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – MACARTHYS LABORATORIES T/A MARTINDALE PHARMA (AN ETHYPHARM GROUP COMPANY) – VENLAFAXINE XL 150MG PROLONGED RELEASE TABLETS

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY Medicines Policy Team







MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Distribute to Pharmacy / Wholesaler Level

Date: 16 March 2023 EL (23)A/10 Our Ref: MDR 072-10/22

Dear Healthcare Professional,

Macarthys Laboratories t/a Martindale Pharma (an Ethypharm Group Company)

Venlafaxine XL 150mg prolonged-release tablets

PL01883/0340

SNOMED Code 41468211000001100

Batch Number	Expiry Date	Pack Size	First Distributed
LC70019	08 2025	30	10/02/2023
LC70020	08 2025	30	13/02/2023

Active Pharmaceutical Ingredient: venlafaxine hydrochloride

Venlafaxine XL 225mg prolonged-release tablets

PL01883/0341

SNOMED Code 41482811000001100

Batch Number	Expiry Date	Pack Size	First Distributed
LC70053	08 2025	30	09/02/2023
LC70054	08 2025	30	Not yet distributed

Active Pharmaceutical Ingredient: venlafaxine hydrochloride

Venlafaxine XL 300mg prolonged-release tablets

PL01883/0363

SNOMED Code 37997111000001100

Batch Number	Expiry Date	Pack Size	First Distributed
LC69693	07 2024	30	Not yet distributed
LC69699	07 2024	30	Not yet distributed
LC69701	07 2024	30	Not yet distributed

Active Pharmaceutical Ingredient: venlafaxine hydrochloride

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Brief description of the problem:

Additional to the batches included in the previous Class 4 Medicines Notification (reference <u>EL(22)A/47</u>), Martindale Pharma has made the MHRA aware that the GTIN in the 2D barcode and the printed variable data represents the branded version of the product (Venlalic[®] XL prolonged-release tablets). It should instead reflect the generic name: Venlafaxine XL prolonged-release tablets. The code under the preprinted barcode is correct.

Advice for healthcare professionals:

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. In November 2022, Martindale Pharma had confirmed that no other batches were impacted. However, due to manufacturing issues, additional batches are now impacted by the same issue, including some batches that have not been distributed yet. Due to the market share of this product and consideration of the overall supply position, the batches above are not being recalled and continued distribution of the batches listed in the notification will take place.

Healthcare professionals are advised to exercise caution when dispensing the products. Additional precautions should be considered by wholesalers and pharmacies using automated inventory systems to dispense the affected batch within the pharmacy or wholesale facility.

Advice for patients:

This notification relates to a barcode error on the outer packaging of the product. The medicine itself is not affected and patients do not need to take any action.

Further Information:

For further information, medical enquiries and stock information, contact: <u>Licensed@ethypharm.com</u>

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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