Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

30 January 2024

Dear Healthcare Professional,

DRUG ALERT CLASS 4 DRUG ALERT 3 2024 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – CADILA PHARMACEUTICALS UK LTD – PANTOPRAZOLE 40MG GASTRO-RESISTANT 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 & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Pharmacy/Wholesaler Level

Date: 30 January 2024 EL (24)A/03 Our Ref: MDR 098-01/24

Dear Healthcare Professional,

Cadila Pharmaceuticals (UK) Limited

Pantoprazole 40 mg Gastro-Resistant Tablets **PL 45841/0018**

SNOMED Code: 38419011000001108

Batch No	Expiry Date	Pack Size	First Distributed
ET571E3001	May 2025	28	18/10/2023
ET571E3002	May 2025	28	26/09/2023
ET571E3003	May 2025	28	13/09/2023
ET571E3004	May 2025	28	13/09/2023
ET571E3005	Jun 2025	28	20/11/2023
ET571E3006	Jun 2025	28	17/01/2024
ET571E3007	Jun 2025	28	19/12/2023
ET571E3008	Jun 2025	28	Not yet distributed

Active Pharmaceutical Ingredient: Pantoprazole as sodium sesquihydrate

Brief description of the problem
Crescent Pharma Limited has informed the MHRA regarding an error with the European Article Number (EAN) barcode on the cartons of the above-mentioned batches of Pantoprazole 40 mg Gastro-Resistant Tablets distributed by Crescent Pharma Limited. When scanned, the EAN barcode identifies the product as Bicalutamide 150 mg Tablets. The other product details on the carton, including the name, strength and pharmaceutical form of the medicine are correct. The Global Trade Item Number (GTIN) code printed on the pack and included in the 2D falsified medicines directive (FMD) barcode is correct.

Advice for healthcare professionals
Product quality of the Pantoprazole 40 mg Gastro-Resistant Tablets is not impacted by this issue, therefore the affected batches are not being recalled. Healthcare professionals and recipients of this notification are advised not to use these batches of medicine in robotic or automated dispensing or stocking systems and to carry out manual dispensing and stocking, as appropriate.

Cadila Pharmaceuticals (UK) Limited and Crescent Pharma Limited have confirmed that all future batches of the product will have the correct EAN barcode.

Advice for patients

No action is needed from patients. The issue is related to the wrong barcode on the cartons of the listed batches of Pantoprazole 40 mg Gastro-Resistant Tablets and will be controlled by the healthcare professional dispensing the medication. The quality of the medication itself is not affected.

Patients should continue to take medicines from these batches as prescribed by your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further information
For medical information enquiries please contact pharmacovigilance-eu@cadilapharma.com or telephone: +44 1217901596

For stock control enquiries please contact info@crescentpharma.com or telephone: 01256 772730

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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