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IMMEDIATE MESSAGE TO:

- 1. Directors of Pharmacy
- 2. Medical Directors NHS Boards
- 7 October 2024

Dear Healthcare Professional,

DRUG ALERT CLASS 3 DRUG ALERT 47 2024 – CLASS 3 MEDICINES RECALL – ACTION WITH 5 DAYS – VIATRIS UK HEALTHCARE LTD – TRANDOLAPRIL 2MG & 4MG CAPSULES

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

MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days Pharmacy/Wholesaler Level Recall

Our Ref: DMRC-31208200

Dear Healthcare Professional,

Date: 07 October 2024

Viatris UK Healthcare Ltd

Trandolapril 2mg capsules

SNOMED Code 13694511000001100

| Batch No | Expiry Date | Pack Size | First Distributed |
|----------|-------------|-----------|-------------------|
| 1208031 | Jun-25 | 28 | 22-Feb-23 |
| 1210889 | Sep-25 | 28 | 28-Jun-23 |
| 1210890 | Oct-25 | 28 | 14-Jul-23 |
| 1305267 | Apr-26 | 28 | 11-Sep-23 |
| 1309346 | Sep-26 | 28 | 02-Apr-24 |
| 1309514 | Sep-26 | 28 | 20-May-2024 |

Trandolapril 4 mg capsules

PL 04569/0820

SNOMED Code 13694911000001107

| Batch No | Expiry Date | Pack Size | First Distributed |
|----------|-------------|-----------|-------------------|
| 1210643 | Oct-25 | 28 | 30-May-23 |
| 1305411 | Feb-26 | 28 | 10-Sep-23 |
| 1305413 | Apr-26 | 28 | 17-Dec-23 |
| 1308126 | Apr-26 | 28 | 04-Mar-24 |
| 1309520 | Sep-26 | 28 | 20-Mar-24 |

Active Pharmaceutical Ingredient: trandolapril

Brief description of the problem

Generics (UK) Ltd T/A Mylan UK is recalling specific batches of trandolapril after re-testing showed out of specification results. The listed batches are being recalled as a precautionary measure after testing showed variability of the Trandolapril content. Note: the problem is limited to the batches listed in this notification.

Advice for healthcare professionals

Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

PL 04569/0819

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Medicines & Healthcare products Regulatory Agency

Advice for patients

No action is required by patients as this recall is being undertaken at a Pharmacy and Wholesaler level as a precautionary measure. 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 <u>MHRA Yellow Card</u> <u>scheme</u>.

Further Information

For medical information enquiries please contact Viatris UK Healthcare Limited Medical Information at +44 (0)1707 853 000 (select option 1) or info.uk@viatris.com.

For stock control enquiries please contact Customer Services at +44 (0)1707 853 000 (select option 2).

Recipients of this Medicines Recall 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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