Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days Pharmacy/Wholesaler Level Recall

EL (24)A/35

Our Ref: MDR 113-05/24

Dear Healthcare Professional,

Date: 08 August 2024

Accord-UK Ltd

Trandolapril 0.5mg Capsules

PL 0142/0937

SNOMED Code 14406911000001102

Batch No	Expiry Date	Pack Size	First Distributed
1909343	Aug-24	14	24-Dec-2019
1003165	Feb-25	14	19-May-2020
1003848	Feb-25	14	04-Jun-2020
1009756	Apr-25	14	10-Nov-2020
1009755	Jun-25	14	13-Nov-2020
1101732	Aug-25	14	15-Jun-2021

Trandolapril 2mg Capsules

PL 0142/0939

SNOMED Code 14408411000001106

Batch No	Expiry Date	Pack Size	First Distributed
1105358	Mar-26	28	13-Jul-2021
1203753	Feb-27	28	28-Jun-2022
1203754	Apr-27	28	12-Jul-2022
1206236	Jun-27	28	13-Sep-2022
1206237	Jun-27	28	28-Nov-2022
1210785	Oct-27	28	08-Mar-2023
1300480	Dec-27	28	18-Apr-2023
1301041	Dec-27	28	30-May-2023
1305174	Apr-28	28	20-Oct-2023
1401190	Dec-28	28	07-Jun-2024

Medicines & Healthcare products Regulatory Agency

Trandolapril 4mg Capsules

PL 0142/0940

Batch No	Expiry Date	Pack Size	First Distributed
1008652	Aug-25	28	21-Oct-2020
1010286	Aug-25	28	19-Jan-2021
1105356	Mar-26	28	22-Jun-2021
1202967	Mar-27	28	18-Jul-2022
1207436	Jun-27	28	02-Mar-2023
1401189	Dec-28	28	31-May-2024

SNOMED Code 14409011000001107

Active Pharmaceutical Ingredient: Trandolapril

Brief description of the problem

Accord-UK Ltd is recalling the above batches after retesting showed out of specification results. The listed batches are being recalled as a precautionary measure after testing showed variability of the Trandolapril content beyond permitted levels. Note: the problem is limited to the batches listed in this notification.

Advice for healthcare professionals

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

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 Accord-UK Ltd Medical Information Department on 01271 385257

For stock control enquiries please contact Accord- UK Ltd Customer Services Team on 0800 373573.

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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