Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

T: 0131-244-2528
E: irene.fazakerley@gov.scot

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Board

23 October 2025

Dear Healthcare Professional,

DRUG ALERT CLASS 4 – No 44 2025 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – RELONCHEM LTD – VARIOUS PRODUCTS

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, EL(25)A/44

Caution In Use

Issued 23 October 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

RelonChem Ltd

MEDICINE DETAILS

Losartan Potassium 50mg coated tablets

PL: 45841/0015

Active Ingredient: losartan potassium

SNOMED code: 38933111000001104

GTIN: 5055144202617

No batches within expiry date currently in the market

MEDICINE DETAILS

Losartan Potassium 100mg coated tablets

PL: 45841/0013

Active Ingredient: losartan potassium

SNOMED code: 38933311000001102

GTIN: 5055144202624

No batches within expiry date currently in the market

MEDICINE DETAILS

Losartan potassium/Hydrochlorothiazide 50mg/12.5mg coated tablets

PL: 20395/0109

Active Ingredient: losartan potassium and hydrochlorothiazide

SNOMED code: 45410711000001109

GTIN: 5055144202617

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
NG4001	JUL/2027	28	04/07/2025
NG4002	AUG/2027	28	04/07/2025
NG5001	MAR/2028	28	30/07/2025

MEDICINE DETAILS

Losartan potassium/Hydrochlorothiazide 100mg/25mg coated tablets

PL: 20395/0108

Active Ingredient: losartan potassium and hydrochlorothiazide

SNOMED code: 45411011000001103

GTIN: 5055144202624

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
NH4001	JUL/2027	28	07/07/2025
NH4002	AUG/2027	28	07/07/2025
NH5001	MAR/2028	28	31/07/2025

MARKETING AUTHORISATION HOLDER (MAH)

RelonChem Ltd

MEDICINE DETAILS

Risperidone 0.5mg Tablets (Almus livery)

PL: 20395/0290

Active Ingredient: Risperidone

SNOMED code: 18507611000001104

EAN: 5055382308676

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
151061	APR/2028	20	15 Aug 2025

Background

Losartan potassium & Losartan potassium/hydrochlorothiazide tablets

Relonchem Ltd has informed the MHRA that duplicate GTIN numbers have been assigned to Losartan potassium/Hydrochlorothiazide 50mg/12.5mg and 100mg/25mg coated tablets in error. The GTIN numbers were originally assigned to Losartan Potassium 50mg coated tablets and Losartan Potassium 100mg coated tablets, respectively. The reused barcodes were reported to the Defective Medicines Report Centre (DMRC) by a pharmacy that uses robotic dispensing. The following products have the duplicated barcodes:

- Losartan potassium/Hydrochlorothiazide 50mg/12.5mg coated tablets have the same GTIN number as Losartan Potassium 50mg coated tablets.

- Losartan potassium/Hydrochlorothiazide 100mg/25mg coated tablets have the same GTIN number as Losartan Potassium 100mg coated tablets.

The other product details on the carton, including the name, strength and pharmaceutical form of the medicine are correct. The quality of the medicine is not impacted by the labelling defect. There are no batches of Losartan potassium 50mg and Losartan potassium 100mg currently on the market within expiry date.

Risperidone 0.5mg Tablets (Almus livery)

Relonchem Ltd has informed the MHRA that a duplicate EAN number has been assigned to Risperidone 0.5mg tablets. The EAN number, 5055382308676, was originally assigned to Lansoprazole 30mg gastro-resistant capsules. The products that have the same barcode are:

- Lansoprazole 30mg gastro-resistant capsules (28) – PIP1149640 (batch 29977) - MAH TEVA
- Risperidone 0.5mg tablets (20) – PIP1159094 (batch 151061) – MAH RelonChem

For all impacted products the other product details on the carton, including the name, strength and pharmaceutical form of the medicine are correct. The quality of the medicine is not impacted by the labelling defect.

Advice for Healthcare Professionals:

Healthcare professionals are advised to use caution and consider extra safeguards for these batches in robotic or automated dispensing system or stocking systems and should carry out manual dispensing and stocking, as appropriate. Pharmacy providers should also consider local assessments, in line with this notification and inform Relonchem Ltd of any stock that cannot be used in an automated dispensing system.

Losartan potassium & Losartan potassium/hydrochlorothiazide tablets

- The product quality of the Losartan Potassium 50mg and 100mg coated tablets and Losartan potassium/Hydrochlorothiazide 50mg/12.5mg and 100mg/25mg coated tablets are not impacted by this issue, therefore the affected batches are not being recalled.
- RelonChem Ltd have advised that a further 132 units of Losartan potassium/Hydrochlorothiazide 50mg/12.5mg and 4780 units of Losartan potassium/Hydrochlorothiazide 100mg/25mg will be released to the market to meet customer orders and supply requests. Stock will be marketed until 30 Nov 2025 and all new batches marketed after this date will be packed with the new GTIN barcodes.
- All remaining stock of Losartan Potassium 50mg and 100mg coated tablets will not be onward distributed and future batches of Losartan Potassium 50mg and 100mg coated tablets will be marketed with the new GTIN barcodes.

Risperidone 0.5mg Tablets (Almus livery)

- The product quality of the Risperidone 0.5mg tablets in Almus livery is not impacted by this issue, therefore the affected batches are not being recalled.
- RelonChem Ltd have confirmed that no further product will be distributed with the duplicated barcodes. All new batches produced by the manufacturing site and distributed, will be packed with new EAN barcodes.

Advice for Healthcare Professionals to Provide to Patients:

No action is needed from patients, continue to take medication from these batches as prescribed by your healthcare professional. The product quality and safety of the tablets are not affected by this issue. 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 their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Additional information:

For all medical information enquiries and information on this product, please email medicalinformation@relonchem.com, or telephone 0151 556 1860.

For stock control enquiries please email medicalinformation@relonchem.com, or telephone 0151 556 1860.

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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk