Chief Medical Officer Directorate
Pharmacy and Medicines Division

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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

17 April 2025

Dear Healthcare Professional,

DRUG ALERT CLASS 2 – No 17 2025 – CLASS 2 MEDICINES RECALL – ACTION WITHIN 48 HOURS – RECORDIATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A – LERCANIDIPINE HCL 20MG 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

MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(25)A/17

Action within 48 hours

Issued 17 April 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Recordati Industria Chimica e Farmaceutica S.p.A.

MEDICINE DETAILS

Lercanidipine HCl 20mg Tablets

PL: 04595/0011

Active Ingredient: lercanidipine hydrochloride

SNOMED code: 21857911000001106

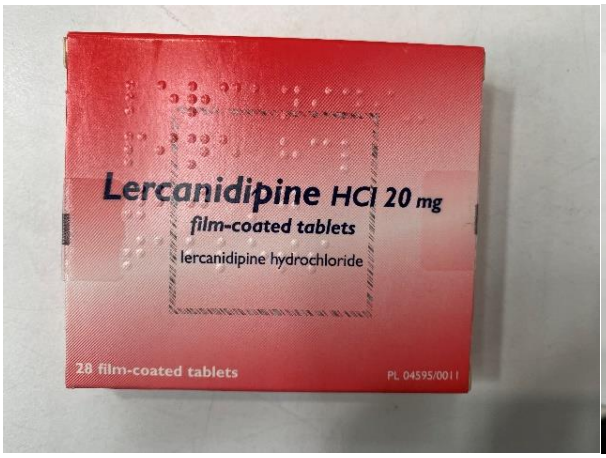
GTIN: 8057742821983

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
MD4L07	01/2028	28	10/04/2025

Background

Recordati Pharmaceuticals Limited has informed the MHRA of an error in the strength of the product printed on some of the faces (sides) of the product carton. The error is limited to the batch of Lercanidipine HCl 20mg Tablets listed in the table above. The packs of 20mg tablets are incorrectly labelled as 10mg on some sides of the product carton. The correct strength (20mg) is printed on the top of the carton and on the blister strips. Recordati Pharmaceuticals Limited is initiating a recall of the specified batch as a precautionary measure.



Advice for Healthcare Professionals:

Stop supplying the above batch immediately. Quarantine all stock and return it to your supplier using your supplier's approved process. This medicine is being recalled as a precautionary measure.

Pharmacists who have been supplied this batch and suspect they have dispensed the tablets to patients should contact the patient immediately to make them aware of this error. Please see 'advice for patients' section below.

Advice for Patients:

Patients who have been prescribed 10 mg tablets **and** have received tablets with this batch number (printed on the foil of the blister strips) should contact your pharmacist or GP immediately. In the event that the GP or pharmacist cannot be reached, please call NHS 111 for advice on continuing your medication. In the event you cannot speak to a healthcare professional before you are due to take your next dose:

1. verify the strength of the tablets is 20 mg from the information on the foil of the blister strips
2. remove one tablet from the blister as normal
3. locate the break line on the tablet
4. snap the tablet in half across the break line and take half of the tablet. This is permitted for the 20mg tablets and is in line with information included in the patient information leaflet (where it states 'The tablet can be divided into equal doses').

Patients who have been prescribed 20 mg tablets should verify the strength of the tablets by checking the information on the foil of the blister strips prior to taking the tablet. Continue to take the tablets as prescribed by your doctor.

Do not stop taking your medicine without consulting your healthcare provider. Patients who are concerned about the strength of the medication they have received should check it with their dispensing pharmacy.

Patients concerned they may have accidentally taken a higher dose of the medication than they were prescribed should seek medical attention.

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.

Additional information:

For all medical information enquiries and information on this product, please email medinfo@recordati.co.uk, or telephone +353 (0)87 6245669.

For stock control enquiries please email customerservice@recordati.com, or telephone 01491 576 336.

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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