

MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(25)A/53

Action within 48 hours

Issued 11 December 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Hameln Pharma Ltd

MEDICINE DETAILS

Clarithromycin 500 mg powder for concentrate for solution for infusion

PL: 01502/0135

Active Ingredient: **Clarithromycin lactobionate**

SNOMED code: **36236311000001104**

GTIN: **05016386000218**

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
23J097	30/09/2027	10	07/11/2023
23J098	30/09/2027	10	11/12/2023
23J099	30/09/2027	10	08/01/2024
23J100	30/09/2027	10	09/02/2024
24A227	30/11/2027	10	10/05/2024
24A230	31/12/2027	10	12/08/2024
24E038	31/01/2028	10	22/08/2024
24E039	29/02/2028	10	17/09/2024
24E040	29/02/2028	10	03/10/2024
24G130	30/04/2028	10	11/11/2024

24G330	30/04/2028	10	28/11/2024
24G331	30/04/2028	10	03/12/2024
24G333	30/06/2028	10	30/12/2024
24I243	31/07/2028	10	07/01/2025
24I245	31/07/2028	10	20/01/2025
24I400	31/07/2028	10	03/02/2025
24I402	30/09/2028	10	12/02/2025
24I403	30/09/2028	10	04/03/2025
24I404	30/09/2028	10	25/03/2025
24I418	30/09/2028	10	14/04/2025
24K161	31/10/2028	10	28/04/2025
24K162	31/10/2028	10	16/05/2025
24K163	31/10/2028	10	27/05/2025
24K164	30/11/2028	10	27/05/2025
24K165	30/11/2028	10	16/06/2025
24K166	30/11/2028	10	08/07/2025
24K167	30/11/2028	10	04/08/2025
24K168	30/09/2028	10	24/04/2025
25D674	31/03/2029	10	26/08/2025
25D675	31/03/2029	10	19/09/2025
25F174	31/05/2030	10	09/10/2025
25F175	31/05/2030	10	31/10/2025
25F263	31/05/2030	10	19/11/2025

Background

Hameln Pharma Ltd is recalling the batches of Clarithromycin 500 mg powder for concentrate for solution for infusion listed in the table.

Following an inspection of the clarithromycin lactobionate raw material manufacturer, the certification of suitability for use in medicines was withdrawn due to non-compliance with Good Manufacturing Practice.

The affected batches of Clarithromycin 500 mg powder for concentrate for solution for infusion are listed in the table above.

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.

Hameln Pharma Ltd has not received an increase in reports of adverse events or product quality complaints in connection with these batches. The recall is being undertaken as a precautionary measure.

The recall only applies to the batch numbers listed in the table, which were manufactured with the affected raw material. Other batches of Clarithromycin 500 mg powder for concentrate for solution for infusion are not impacted.

Replacement batches of Clarithromycin 500 mg powder for concentrate for solution for infusion are available from Hameln Pharma Ltd and ongoing supplies will be maintained.

Advice for Healthcare Professionals to Provide to Patients:

Patients are not required to take any action. This product is administered by healthcare professionals in a hospital or healthcare setting.

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 drug.safety@hameln-pharma.co.uk or telephone +44 (0)1452 621 661.

For stock control enquiries please email customer.services@hameln-pharma.co.uk , or telephone +44 (0)1452 621 661.

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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