



MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy/Wholesaler Level Recall

Date: 19 August 2024

EL (24)A/39

Our Ref: MDR 113-05/23

Dear Healthcare Professional,

Glenmark Pharmaceuticals Europe Ltd

Fingolimod 0.5 mg Hard Capsules

PL 25258/0323

SNOMED Code 41463711000001102

Batch No	Expiry Date	Pack Size	First Distributed
1306526	31-May-2025	28	17-Oct-2023
1306528	31-May-2025	28	06-Feb-2024
1400709	30-Nov-2025	28	27-Feb-2024
1400710	30-Nov-2025	28	15-Mar-2024

Active Pharmaceutical Ingredient: Fingolimod Hydrochloride

Brief description of the problem

Glenmark Pharmaceuticals Europe Ltd is recalling the above batches after retesting showed out of specification results. The tabled batches are being recalled as a precautionary measure after testing showed variability of the capsule contents beyond permitted levels.

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 further 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 [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please use the following options: by phone +44 8004 580 383 or email medical_information@glenmarkpharma.com

For stock control enquiries please email orders.uk@glenmarkpharma.com



Medicines & Healthcare products Regulatory Agency

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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