MEDICINES RECALL

CLASS 3 MEDICINES RECALL, EL(26)A/02

Action within 5 days

Issued 21 January 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Glenmark Pharmaceuticals Europe Limited

MEDICINE DETAILS

Fingolimod Glenmark 0.5 mg Hard Capsules

PL: 25258/0323

Active Ingredient: fingolimod hydrochloride

SNOMED code: 41463711000001102

GTIN: 05060204167041

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
1501919	29/02/2027	28	09/10/2025

Background

Glenmark Pharmaceuticals Europe Limited is recalling the above batch after stability testing showed out-of-specification results. The batch is being recalled as a precautionary measure following test results that showed a delay in capsule dissolution.

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 Healthcare Professionals to Provide to 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.

Additional information:

For medical information enquiries please email medical_information@glenmarkpharma.com or telephone +44 8004 580 383

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

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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