MEDICINES RECALL

CLASS 3 MEDICINES RECALL, EL(25)A/49

Action within 5 days

Issued 20 November 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Sun Pharmaceutical Industries Limited

MEDICINE DETAILS

Fingolimod SUN 0.5mg hard capsules

PL 31750/0173

Active Ingredient: fingolimod (as hydrochloride)

SNOMED code: 41496911000001109

GTIN: 8718531949683

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
HAF2945A	30/11/2027	28	08/05/2025

Background

Sun Pharma UK Limited is conducting a precautionary recall of a single batch of Fingolimod SUN 0.5 mg hard capsules due to reports of capsule breakage on removing from the blister. No other batches of Fingolimod SUN 0.5mg hard capsules are impacted.

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:

Patients who have received Fingolimod SUN 0.5mg hard capsules from batch HAF2945A are advised to continue to take the capsules and, where possible, pierce the foil before removing the capsule. The capsule contents are not impacted by this issue. Patients who are experiencing capsules breaking upon removal from the blister should speak to their dispensing pharmacist in the first instance.

The recall is being actioned at the wholesaler and pharmacy levels.

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 Cserv.uk@sunpharma.com, or telephone 020 8848 5050 / 07974754551

For stock control enquiries please email Cserv.uk@sunpharma.com, or telephone 020 8848 5050.

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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