

MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(26)A/37

Action within 48 hours

Issued 20 August 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Zentiva Pharma UK Limited

MEDICINE DETAILS

Fingolimod Zentiva 0.5 mg Capsules

PL: 17780/0858

Active Ingredient: Fingolimod

SNOMED code: 40459211000001106

GTIN: 8594739260931

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
4L01372H	11/2027	28	28 January 2025

Background

Zentiva UK Pharma Limited are recalling one batch of Fingolimod Zentiva 0.5 mg Capsules (BN 4L01372H) as a precautionary measure due to a potential risk of contamination with metal particles. The particles, if present, are known to be small and pose a low risk to the safety or efficacy of the capsules. No reports have been received to date, the particles were identified during shelf-life testing.

Advice for Healthcare Professionals:

Stop supplying the affected batch. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Advice for Healthcare Professionals to Provide to Patients:

If patients have the affected batch they should contact their pharmacy in the first instance. Do not stop taking your medication without speaking to your healthcare professional first. The particles, if present, are known to be small and pose a low risk to the safety of the product. Patients with this batch are not considered at risk and no reports of harm have been reported for this batch of capsules.

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 UKMedInfo@zentiva.com, or telephone 0800 090 2408.

For stock control enquiries please email ukcustomerservices@zentiva.com, or telephone 01371 822022.

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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU

Telephone +44 (0)20 3080 6574

DMRC@mhra.gov.uk