MEDICINES RECALL

CLASS 3 MEDICINES RECALL, EL(25)A/48 Action within 5 days

Issued 11 November 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Sun Pharmaceutical Industries Limited

MEDICINE DETAILS

Atorvastatin 20 mg Film-coated Tablets

PL 14894/0714

Active Ingredient: atorvastatin calcium trihydrate

SNOMED code: 22940911000001103

GTIN: 05015525012327

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PTF6133A	30/11/2027	28	09/09/2025

Atorvastatin 80 mg Film-coated Tablets

PL: 14894/0716

Active Ingredient: atorvastatin calcium trihydrate

SNOMED code: 22941511000001103

GTIN: 05015525012341

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PTF5991D	30/11/2027	28	19/08/2025
PTF5991F	30/11/2027	28	27/08/2025

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Background

Sun Pharma UK Limited are recalling the batches of tablets specified in the table as a precautionary measure due to failing dissolution test results reported during ongoing stability studies.

Advice for Healthcare Professionals:

Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process

Advice for Patients:

Patients should continue to take medicines as prescribed by your healthcare professional. The recall is being actioned at the wholesaler level as a precautionary measure. No complaints of harm or lack of efficacy have been received from patients regarding this batch.

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

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

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