MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days Pharmacy/Wholesaler Level Recall

Date: 5 June 2024 EL (24)A/19 Our Ref: MDR 078-05/24

Dear Healthcare Professional,

Neuraxpharm UK Ltd

Atomoxetine 10mg Capsules

PL 49718/0010

SNOMED Code 37858111000001106

Batch No	Expiry Date	Pack Size	First Distributed
1211145	09/2025	7	23/02/2023
1203816	03/2025	7	07/07/2022

Atomoxetine 18mg Capsules

PL 49718/0011

SNOMED Code 37858311000001108

Batch No	Expiry Date	Pack Size	First Distributed
1211146	09/2025	7	23/02/2023

Atomoxetine 25mg Capsules

PL 49718/0012

SNOMED Code 37858511000001102

Batch No	Expiry Date	Pack Size	First Distributed
1211147	06/2025	7	23/02/2023
1207940	06/2025	7	24/10/2022

Atomoxetine 40mg Capsules

PL 49718/0013

SNOMED Code 37900111000001107

Batch No	Expiry Date	Pack Size	First Distributed
1211148	09/2025	7	23/02/2023
1203818	03/2025	7	07/07/2022

Active Pharmaceutical Ingredient: Atomoxetine

Brief description of the problem

Neuraxpharm UK 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.

EL (24)A/19 Page 1 of 2



Medicines & Healthcare products Regulatory Agency

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

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 contact medinfo-uk@neuraxpharm.com or telephone +44 (0) 118 211 4039

For stock control enquiries please contact <u>info-uk@neuraxpharm.com</u> or telephone +44 (0) 118 211 4039

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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EL (24)A/19 Page 2 of 2