Medisource Ireland Limited,
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Batch Recall

Atomoxetine Capsules, USP 25mg
Atomoxetine Capsules, USP 40mg

Exempt Medicinal Products
(Glenmark Pharmaceuticals Inc livery)

Product Name	Batch No.	Expiry
Atomoxetine Capsules, USP 25mg	19233795	2025/08/31
	19241477	2026/03/31
	19242599	2026/06/30
	19243162	2026/07/31
	19243163	2026/07/31
	19243884	2026/09/30
	19243887	2026/09/30
Atomoxetine Capsules, USP 40mg	19234109	2025/09/30
	19234897	2025/11/30
	19240501	2026/01/31
	19241806	2026/04/30

06/02/2025

Dear Pharmacist,

We wish to advise you that the above batches of Atomoxetine Capsules USP are being recalled with immediate effect. These batches have been supplied to you as an exempt medicinal product (EMP) by Medisource or United Drug.

This recall is going to **pharmacy level.** This action has been agreed with the Health Products Regulatory Authority (HPRA).

The recall is due to the presence of a nitrosamine impurity, N-Nitroso Atomoxetine at levels which exceed the current acceptable intake.

You are requested to please take the following actions:

1. Check your current inventory and immediately quarantine any units of the above batches within your pharmacy. For hospital pharmacies, this includes units at wards, clinics and any other relevant locations within the hospital.

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2. If you have supplied units from these batches to any other pharmacy, clinic or other such establishment, forward a copy of this recall letter to them, and request they quarantine and return any unused units to you.

3. Contact your supplier to arrange the return of quarantined stock. Full credit will be issued for stock that has been returned prior to 21st of February 2025.

Alternative replacement stock is currently available to order.

We apologise for any inconvenience this recall action may cause. Should you have any queries, please contact Ríona Howard on telephone number 01-2866366 or email Riona.Howard@medisource.ie.

Adverse events should be reported to regulatory@medisource.ie and to the HPRA (medsafety@hpra.ie).

Yours sincerely,

Riona Howard
Digitally signed by Riona Howard
Date: 2025.02.06 14:05:57 Z

Ríona Howard
Quality & Regulatory Specialist/Responsible Person
Medisource Ireland Ltd