

**Batch Recall****Atomoxetine Capsules, USP 80mg  
Exempt Medicinal Product  
(Glenmark Pharmaceuticals Inc livery)**

| Batch number | Expiry     |
|--------------|------------|
| 19234153     | 2025/09/30 |
| 19234929     | 2025/11/30 |

11-Feb-2025

Dear Pharmacist,

We wish to advise you that the above-listed batches of Atomoxetine Capsules, USP 80mg are being recalled with immediate effect. These batches have been supplied to you as an exempt medicinal product (EMP) by Uniphar.

This recall is going to pharmacy level and the 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 that exceed the current acceptable intake.

Please perform the following actions:

1. Check your current inventory and immediately quarantine any units of the batches which you have in your pharmacy. For hospital pharmacies, this includes units at wards, clinics and any other relevant locations within the hospital.
2. If you have supplied units from the above-listed batches to any other pharmacy or any other healthcare facility, please contact them and request that they return any unused units to you.
3. Return quarantined stock to Uniphar by 25-Feb-2025 where full credit will be issued to you.

Replacement stock is not available to order.

Suspected adverse reactions should be reported to [psquality@uniphar.ie](mailto:psquality@uniphar.ie) and the Health Products Regulatory Authority ([medsafety@hpra.ie](mailto:medsafety@hpra.ie)).

**Uniphar Group  
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We apologise for any inconvenience this action may cause. Should you have any queries, please contact Eileen Carroll at [psquality@uniphar.ie](mailto:psquality@uniphar.ie) at telephone number: +353 (0)1-4687660.

Yours sincerely,

A handwritten signature in blue ink, followed by the date '12-Feb-2025' written in the same ink.

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Eileen Carroll  
On Demand Ireland Quality Lead

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