

Batch Recall

**Duloxetine Accord 30 mg hard gastro-resistant capsules, PA2315/268/001
Batch no. 230804, Expiry Date: 03/2026**

**Duloxetine Accord 60 mg hard gastro-resistant capsules, PA2315/268/002
Batch no. 230797, Expiry Date: 02/2026**

28th March 2024

Dear Pharmacist,

We wish to advise you that the above referenced batches of Duloxetine Accord hard gastro-resistant capsules are being recalled with immediate effect.

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

The reason for the recall is due to the detection of N-nitroso-duloxetine.

You are requested to please take the following actions:

1. Please immediately quarantine any units of the batches which you have in your pharmacy. For hospital pharmacists, this request includes stock on wards, in clinics and at any other relevant locations within your hospital.
2. Please return quarantined units to your supplier, indicating that they are being returned as a result of this recall action. The final date for recalled stock to be received back for credit is 12th April 2024.
3. If you have supplied units from these batches to any other pharmacy, clinic or other such establishment, please forward a copy of this recall letter to them, and request they quarantine and return any unused units to you.

Replacement stock is currently unavailable.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Accord Healthcare Ireland Ltd. at telephone number +353 21 4619040 or email qa_ireland@accord-healthcare.com.

Yours sincerely,



Wojciech Kisiel, Responsible Person