

Batch Recall

Product	PA Number	Batch Number	Expiry Date
Bisoprolol Fumarate 1.25mg Tablets	PA0688/014/001	29735M/2	10 2025
		29735M/3	10 2025
		30830M/1	10 2026
Bisoprolol Fumarate 2.5mg Tablets	PA0688/014/002	30711K/1	09 2026
		29709M/4	10 2025
		30725K/1	09 2026
Bisoprolol Fumarate 3.75mg Tablets	PA0688/014/003	30800L/1	10 2026
Bisoprolol Fumarate 5mg Tablets	PA0688/014/004	30678K/1	08 2026
		31085A/2	01 2027
		31160B/1	01 2027
Bisoprolol Fumarate 10mg Tablets	PA0688/014/005	31006A/2	12 2026
		30874M/3	10 2026
		30874M/2	10 2026
		30634J/1	08 2026

02nd July 2025

Dear Pharmacist,

We wish to advise you that the above-listed batches of Bisoprolol Fumarate Tablets are being recalled with immediate effect.

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

The recall is due to levels of a nitrosamine impurity above the acceptable limit.

Please perform the following actions:

1. Immediately identify and quarantine any units of the above batches in your pharmacy. For hospital pharmacists, this includes stock on wards, in clinics and at any other relevant locations within your hospital.
2. 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 15th July 2025.
3. If you have supplied units of 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.

Unimpacted stock is available to order.

We apologise for any inconvenience this action may cause. Should you have any queries, please contact Yvonne Egan at telephone number 091 872515. Please notify any adverse events to Chanelle Medical (chanelle@medinformation.co.uk) and to the HPRA (medsafety@hpra.ie).

Yours sincerely,

Yvonne Egan, Director of Quality & QP