

Batch Recall

Alamycin LA 300 mg/ml Solution for Injection

VPA 22664/039/001

Batch No.: 4495-600C, Expiry Date: Dec 2026

06 June 2025

Dear Wholesaler

Further to our communication dated 03 April 2025 requesting a stop sale on sterile products, we wish to advise you that the above batch of Alamycin LA 300 mg/ml Solution for Injection is being recalled with immediate effect.

This recall is going to **wholesale level**.

This action has been agreed with the Health Products Regulatory Authority.

This recall is precautionary and is due to observations made in relation to aseptic manufacturing and filling.

Please perform the following actions:

1. If you have not already done so, immediately identify and quarantine any units of this batch in your possession.
2. If you have supplied this batch to any other wholesaler, forward those wholesalers a copy of this recall letter, requesting that they quarantine and return any unsold quantities of this batch to you.
3. Complete the attached reconciliation form indicating the number of units quarantined at your organisation and return this form to Barry Mone at Barry.Mone@norbrook.ie within 5 days of receipt of this letter. Please complete the form even if you do not have stock remaining in your facility.

Upon receipt of confirmation of your stock, Norbrook will arrange courier pick up and fully credit your account for product returned to Norbrook by 11 Jul 2025. Please refer to the recall reference number **MDR 01-06/25** in all correspondence or returned shipments.

Unaffected stock is available to order at this time.

We apologise for any inconvenience this action may cause, and we wish to thank you in advance for your assistance.

Should you have any queries please contact Ms Elaine McCullough via telephone number 00442830264435 or email elaine.mccullough@norbrook.co.uk

Sincerely

PP. McBurn

Elaine McCullough, Head of Corporate QA, 0044283026443

Attachment 1: Product Reconciliation Form

Class 3 Batch Recall – Wholesale Level

Norbrook Recall Reference MDR 01-06/25

Please complete this form and return via email within 5 days to Barry Mone at Barry.Mone@norbrook.ie so that we can arrange collection of the product and credit for the returned units.

Product Name	Batch Number	Expiry Date	Number of units quarantined at your facility
Alamycin LA 300 mg / ml Solution for Injection	4495-600C	Dec 2026	

Please indicate the number of units quarantined at your facility for uplift.

Please respond even if you do not have stock remaining in your facility.

Reconciliation completed by:

Name	
Position	
Signature	
Date	

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