ADVANZ PHARMA

Product Recall

Palmeux prolonged-release suspensions for injection in prefilled syringe

All in date batches

Product Name	License Number
Palmeux 50 mg prolonged-release suspension for injection in prefilled syringe	PA1142/040/002
Palmeux 75 mg prolonged-release suspension for injection in prefilled syringe	PA1142/040/003
Palmeux 100 mg prolonged-release suspension for injection in prefilled syringe	PA1142/040/004
Palmeux 150 mg prolonged-release suspension for injection in prefilled syringe	PA1142/040/005

Date: 24th December 2025

Dear Wholesaler,

We wish to advise you that all batches of the above-listed products are being recalled with immediate effect.

The recall is to pharmacy level.

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

This recall is a precautionary measure due to GMP deficiencies identified at the manufacturing site.

You are requested to perform the following actions:

1. Immediately identify and quarantine any units of the above batches which you have in your facility or are returned to you by your customers.
2. If you have supplied these products to any other wholesaler(s), please forward a copy of this recall letter to those wholesalers, requesting that they immediately quarantine any unsold quantities of these products and return those back to you.
3. Return all quarantined units to your supplier. The final date for recalled stock to be received for credit is 19th January 2026.

Unaffected stock is not available to order.

Suspected adverse reactions should be reported to medicalinformation@advanzpharma.com and the Health Products Regulatory Authority (medsafety@hpra.ie).

We sincerely apologise for any inconvenience this action may cause. Should you have any queries regarding this recall please contact Advanzpharma at medicalinformation@advanzpharma.com or telephone number +353 1800 851 119.

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ADVANZ PHARMA

Best regards,

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