

## PRODUCT RECALL RESPONSE FORM

### URGENT DRUG RECALL- RETAIL LEVEL

On Feb 19, 2025, an update to the original recall letter dated Feb 13, 2025, has been made to correct the NDC numbers associated with lot number P300169.

Please complete the required information and fax it to **1-817-868-5362**  
or email to [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)

**To the Attention of Drug Safety/ Recall Services-Zydus Pharmaceuticals USA Inc.**

Product	Vial NDC Number	Carton NDC Number	Lot Number	Expiry Date	No. of Vials/Boxes Purchased	No of the Vials/Boxes consumed	No. of Vials/Boxes in possession	No of Vials/Boxes to be returned
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-8	P300068	Feb-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-1	P300072	Feb-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-1	P300073	Feb-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-1	P300153	Jun-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-8	P300154	Jun-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1839-1	70710-1839-8	P300169	Jun-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-1	P300195	Aug-2025				

**Office of Regulatory Affairs**

**Zydus Pharmaceuticals (USA) Inc.**

(A wholly owned subsidiary of Zydus Lifesciences Limited)

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Product	Vial NDC Number	Carton NDC Number	Lot Number	Expiry Date	No. of Vials/Boxes Purchased	No of the Vials/Boxes consumed	No. of Vials/Boxes in possession	No of Vials/Boxes to be returned
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1839-1	70710-1839-1	P300197	Aug-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-1	P400014	Dec-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-8	P400015	Dec-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-1	P400017	Dec-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-8	P400018	Dec-2025				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-8	P400068	Feb-2026				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-1	P400070	Feb-2026				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-1	P400112	May-2026				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1839-1	70710-1839-1	P400113	May-2026				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-8	P400114	May-2026				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1839-1	70710-1839-8	P400115	May-2026				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-8	P400139	Jul-2026				
Nelarabine Injection 250 mg/50 mL (5 mg/mL)	70710-1726-1	70710-1726-1	P400142	Jul-2026				

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No. of Returns kit required: \_\_\_\_\_

Please mark as applicable

☐ We currently do not have any inventory of the above-listed Lot/bottles

☐ We are notifying our customers

☐ We have identified and notified my customers that were shipped or may have been shipped this product by \_\_\_\_\_;

☐ Attached is the list of customers who received/ may have received this product. Please notify my customers.

Any adverse event associated with recalled product? ☐ Yes ☐ No

If yes, please explain:

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Please check appropriate box to describe your business

☐ Wholesaler/Distributor

☐ Retailers

☐ Repackager

☐ Manufacturer

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\_\_\_ Pharmacy- Retail

\_\_\_ Hospital/ Medical Facility

\_\_\_ Hospital Pharmacies

\_\_\_ Medical Laboratory

\_\_\_ Other: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Tel Number: \_\_\_\_\_

Firm Name: \_\_\_\_\_

DEA# \_\_\_\_\_

Address: \_\_\_\_\_

City/ State: \_\_\_\_\_

Phone number: \_\_\_\_\_

If you have not purchased, the concerned lot directly from Zydus Pharmaceuticals USA Inc., then please provide details of your wholesaler: \_\_\_\_\_ (Name, City) DEA# \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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