69452-00513-01183116
INDEPENDENT PHARMACY DIST. LLC
1107 W MARKET CENTER DR
HIGH POINT, NC 27260

BIONPHARMA®

Bionpharma Inc.
400 Alexander Park
Suite 2-4B
Princeton, NJ 08540
Phone: 609-380-3310

August 7, 2026

URGENT: DRUG RECALL

RE: Doxylamine Succinate and Pyridoxine HCl Delayed-Release tablets 10 mg/10 mg (NDC # 69452-206-20, Lot # DMA25006, Exp. 11/2028, 100's count)

Dear Valued Customer,

We are writing to inform you of a product recall being conducted voluntarily by Bionpharma Inc. for one lot of Doxylamine Succinate and Pyridoxine HCl Delayed-Release tablets 10 mg/10 mg distributed between 4-1-2026 and 7-7-2026. Bionpharma has initiated a recall of the impacted lot, and it is being conducted in cooperation with the Food and Drug Administration (FDA).

NDC #	Impacted Lot #	Expiry Date
69452-206-20	DMA25006	11/2028

A single foreign tablet was found in one 100's count bottle of the above-referenced lot of the product. Based on the investigation, this is an isolated incident with an extremely low frequency of occurrence. The foreign tablet is readily distinguishable from **Doxylamine Succinate and Pyridoxine HCl DelayedRelease tablets 10 mg/10 mg** based on their physical characteristics, including color (white vs. pink), size (8 mm vs 7 mm) and imprint (DP 1 vs B 10). So, one product cannot be mistaken for another. However, out of an abundance of caution, Bionpharma has decided to recall the batch to the retail level.

See enclosed product label for ease in identifying the product at the retail level.

It is important to note that Bionpharma has not received any adverse event reports to date relating to this issue and no other lot of Bionpharma's Doxylamine Succinate and Pyridoxine HCl Delayed-Release tablets 10 mg/10 mg is impacted by this recall.

We request that you take the following actions:

1. Immediately cease distribution of the drug product from the affected lot (Lot # DMA25006) and remove it from active inventory.

2. Please contact our Recall Coordinator and promptly return the attached "Recall Response Form" at the below email address or fax or via mail. Please send the Recall Response Form even if you do not have any product from the affected lot.

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Qualanex, LLC
Qualanex Recall# 513
1410 Harris Road
Libertyville, IL 60048
Phone: 800-505-9291 (Mon-Fri 9AM-5PM CST); Fax: 847-737-3719
Email: recall@qualanex.com

If you have any product from the affected lot, please contact the Recall Coordinator for issuance of a Return Authorization (RA) Form. The RA Form provided will contain all information required to return affected lot (Lot DMA25006) of Doxylamine Succinate and Pyridoxine HCl Delayed-Release tablets 10 mg/10 mg.

3. Credit for any returned merchandise, along with shipping charges, will be reimbursed by credit memo.

4. If you have supplied the impacted lot to retail pharmacies, please take the following steps:

    a. Please forward this Recall Letter along with the attached Recall Response Form to the retailer.

    b. Instruct the retailer to immediately cease distribution of the drug product from the affected lot (Lot # DMA25006) and remove it from active inventory.

    c. Instruct the retailer to complete the attached Recall Response Form and send it to Bionpharma (as explained in #2 above).

If you have any further questions, please feel free to contact me at 919-396-6016 (Mon-Fri 9AM-5PM). Our primary concern is always for the health and safety of our customers.

We appreciate your cooperation and sincerely regret any inconvenience caused by this action.

Kind Regards,

Jerri Lubke

Jerri Lubke
Director, Sales Operations
Bionpharma Inc.
2250 Perimeter Park Drive,
Suite 100, Morrisville, NC 27560

PRODUCT LABEL

NDC 69452-206-20

Doxylamine Succinate and Pyridoxine Hydrochloride Delayed-Release Tablets

10 mg/10 mg

WARNING: Swallow tablets whole. Do not crush, chew, or split the tablets.

Rx only **100 Delayed-Release Tablets**

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Each delayed-release tablet contains:
Doxylamine succinate, USP.....10 mg
Pyridoxine hydrochloride, USP.....10 mg

Usual Dosage: Take two tablets daily at bedtime. If symptoms are not adequately controlled, the dose can be increased to a maximum recommended dose of four tablets daily (one in the morning, one mid-afternoon and two at bedtime).

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Keep container tightly closed. Protect from moisture and light.

3 69452 20620 1

PHARMACIST: Dispense in original container or equivalent air tight, light-resistant container. Dispense accompanying patient package insert to the patient.

Keep out of reach of children.

KR/DRUGS/KTK/28/321/2001 PET005549-US

Distributed by:
Bionpharma Inc.
Princeton, NJ 08540
MADE IN INDIA
0325

Unvarnished Area
50 x 25 mm

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RECALL RESPONSE FORM

RE: Doxylamine Succinate and Pyridoxine HCl Delayed-Release Tablets 10 mg/10 mg (NDC # 69452-206-20, Lot # DMA25006, Exp. 11/2028, 100's count)

Please check ALL appropriate boxes.

☐ I have read and understand the instructions provided in the August 7, 2026 Recall Letter.

☐ I have checked my stock and have quarantined inventory consisting of:

Item code	Product	Lot#	Pack Size	# of units
	Doxylamine Succinate and Pyridoxine HCl Delayed-Release Tablets 10 mg/10 mg (NDC # 69452-206-20)	**DMA25006 Exp. 11/2028**	**100's count**	

☐ I have checked my stock and I don't have any inventory of the affected lot (**Lot # DMA25006**) of **Doxylamine Succinate and Pyridoxine HCl Delayed-Release tablets 10 mg/10 mg**

☐ Please check the appropriate box (es) to describe your business

☐ Distribution Center. If yes,

- Have you identified and notified the retail stores to whom the impacted lot was/may have been shipped? **YES/ NO**
- Number of retail stores to whom the impacted lot was/may have been shipped _____
- How did you send the communication? **EMAIL/FAX/POSTAL MAIL/PHONE**
- When was the notification to retail stores sent _____
- In order to perform an effectiveness check of the recall as required by FDA, please attach a listing of the retail stores to whom the impacted lot was/may have been shipped along with contact details.

☐ Retail/ Store. If yes,

- Have you identified and notified the consumers to whom the impacted lot was/may have been dispensed? **YES/ NO**
- Wholesaler purchased from:
  Name: _____
  Address: _____
- How did you send the communication? **EMAIL/FAX/POSTAL MAIL/PHONE**
- When was the notification to consumers sent ___

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Name: _____

Title: _____

Tel. number: ( ) **Fax. Number: ( )**

Email address: _____

Company name: _____

Address: _____

City/State/Zip: _____

PLEASE FAX/EMAIL/MAIL COMPLETED RESPONSE FORM TO:

Qualanex, LLC
Qualanex Recall# 513
1410 Harris Road
Libertyville, IL 60048
Phone: 800-505-9291; Fax: 847-737-3719
Email: recall@qualanex.com