



*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.

400 Alexander Park, Suite 2-4B, Princeton, NJ 08540
www.bionpharma.com



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

BIONPHARMA



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

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/TKV28/321/2001 PET005549-US

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.



**Unvarnished Area
50 x 25 mm**