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59651-00446-01183116
INDEPENDENT PHARMACY DISTRIBUTOR, LLC
1107 W MARKET CENTER DR
HIGH POINT, NC 27260

# BUSINESS RESPONSE FORM

## Nebivolol Tablets 2.5 mg
**Product Recall – December 6, 2024**
**Recall # 446**

**Please fill out this form completely**. By doing so, this will acknowledge that you have read and understand the Product Recall instructions and have taken the appropriate action.

Customer Name _____DEA # _____
***DEA # is required, if it is not provided, the processing of your form will be delayed.***

Address_____

City_____ State_____ Zip_____

Contact Name (please print)_____ Telephone #_____

Contact E-mail : _____ Fax # _____

Contact Signature _____Date_____

**I have checked my stock and:**

_____Do not have any stock of **recalled items**.

**OR**

I have quarantined and listed in the box below the qty. of withdrawn units, I will be returning to QUALANEX, as soon as possible. Upon receipt of this Response Form, QUALANEX will issue return authorization label(s) Please indicate the # of needed box labels _____.

| Item Description | NDC Number | Lot Number | Sealed Bottle Qty. To Be Returned | Open Bottle Qty. To Be Returned |
|---|---|---|---|---|
| Nebivolol Tablets 2.5 mg | 59651-137-30 | NB0224001A | | |
| | 59651-137-30 | NB0224001B | | |



Aurobindo Pharma USA, Inc. • 6 Wheeling Road • Dayton, NJ 08810
{phone}866.850.2876 • {fax}732.355.9449

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HIGH POINT, NC 27260

## Recall # 446

**If you did not purchase the product directly from the Manufacturer, please complete the below section.**

Purchased From: Wholesaler Name _____

City_____ State_____

Wholesaler DEA#_____

If you have any questions regarding this form or product return, please contact QUALANEX at 888-504-2014. Office hours 7am to 4pm CST Monday through Friday.

**Please fax this form to: 847-737-3719 Or E-mail recall@qualanex.com**



Aurobindo Pharma USA, Inc. • 6 Wheeling Road • Dayton, NJ 08810
{phone}866.850.2876 • {fax}732.355.9449

59651-00446-0118311
INDEPENDENT PHARMACY DISTRIBUTOR, LL
1107 W MARKET CENTER DI
HIGH POINT, NC 2726

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December 06, 2024

# URGENT DRUG RECALL

Dear Valued Customer,

This is to inform you of a product recall involving:

## Product Nebivolol Tablets 2.5 mg

Refer Attachment 1 for NDC, dosage strength, Package Size and Lot details

**See enclosed product label for ease in identifying the product**

Aurobindo Pharma USA, Inc. has initiated a voluntary Drug Product Recall for the product Nebivolol Tablets 2.5 mg from USA market due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso Nebivolol above acceptable intake (AI) limit.

Nebivolol Tablets are indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. To date, Aurobindo has not received any reports of adverse drug events that are confirmed with this recall. Patients who are prescribed Nebivolol should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

As per the product information leaflet, Nebivolol Tablets 2.5 mg are light blue colored, round shaped, biconvex uncoated tablets debossed with 'L' on one side and '78' on the other side.

Aurobindo USA began shipping impacted batches to customers nationwide from June 13, 2024 to November 20, 2024.

Please complete and return the enclosed product return response form (business response form) as soon as possible. Consequently, please examine your inventory and quarantine the product batches subject to this recall. In addition, if you have further distributed these batches, please notify your customers accordingly and contact Qualanex with any questions. The product can be identified by checking the product name and batch or lot number on the product label.

As this recall should be carried out to the retail level, your assistance is appreciated and necessary to ensure patient safety.



Aurobindo Pharma USA, Inc. · 279 Princeton Hightstown Road · East Windsor, NJ 08520-1401
{phone}866.850.2876 · {fax}732.355.9449

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**Recall Instructions:**

Please perform the following activities:

- Immediately examine your inventory and quarantine the specified lots of Nebivolol Tablets 2.5 mg.
- Immediately discontinue the distribution of the specific lots being recalled.
- Promptly complete the Product Return Response Form even if you have no product to return. If you have further distributed this product, notify your customers of this recall by including a copy of this notice.
- In the event you have the recall product, please return it to Qualanex, LLC., using the enclosed postage paid product return label and mail to the following.
  Qualanex, LLC.
  1410 Harris Road
  Libertyville, IL 60048

Completed product response form (Yes) may be return by the following methods:

- Email to recall@qualanex.com
- Fax to 847-737-3719
- Mail to:
  Aurobindo USA C/O Qualanex LLC
  1410 Harris Rd
  Libertyville, IL 60048

Please complete and return the enclosed Product Return Response Form as soon as possible. If you need assistance in returning your product or have questions about the recall process, contact Qualanex at 888-504-2014 during the hours of 7:00 AM to 4:00 PM CST.

Please return your product along with return goods authorization form using postage paid shipping label included in your recall return packet. Once the response form is received, a return authorization will be generated and e-mailed to you to be included with your recall returns. Appropriate reimbursement for the product returns will be issued on the receipt upon the recall product.

This recall is being made with the knowledge of the Food and Drug Administration.



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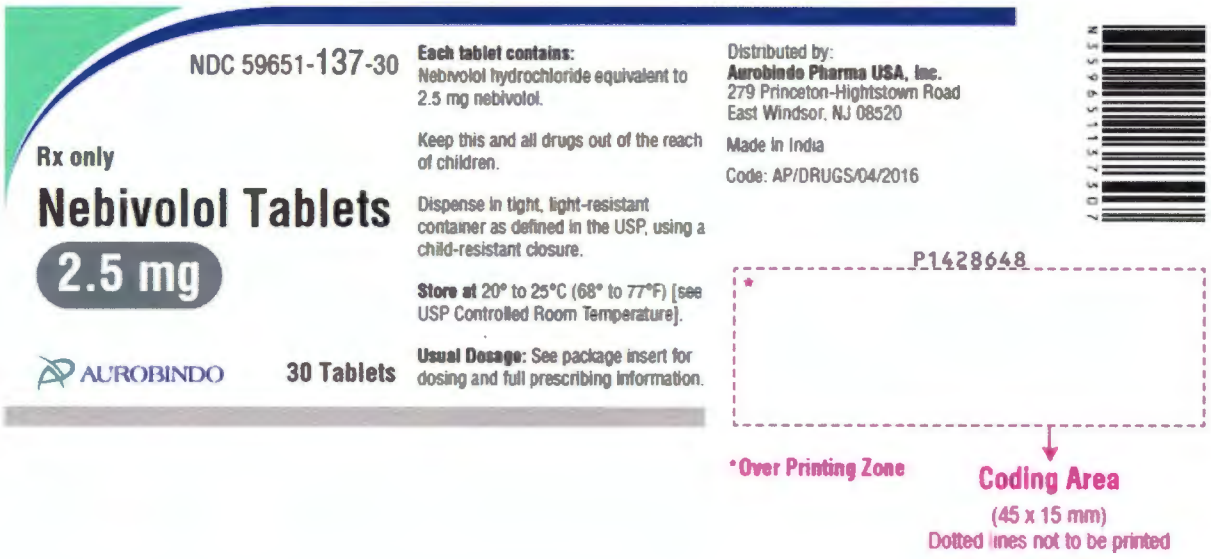
Sincerely,

Linda Torres

Digitally signed by Linda Torres
DN: cn=Linda Torres, o=Aurobindo Pharma LLC, ou=QA Product Complaints, email=ltorres@aurobindousa.com, c=US
Date: 2024.12.06 07:05:26 -05'00'

Ms. Linda Torres
QA Product Complaint Manager
Aurobindo Pharma USA, Inc
279 Princeton-Hightstown Rd
East Windsor, NJ 08520-1401
Direct Email: LTorres@aurobindousa.com
Phone-732-839-9419
Fax-732-289-6189

**The product label is as shown below:**



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## Attachment – 1

### Batches manufactured at APL Healthcare Limited Unit-IV

| NDC Number | Dosage Strength | Package Size | Lot Number | Expiration Date |
|---|---|---|---|---|
| 59651-137-30 | 2.5 mg | 30's HDPE Container | NB0224001A | 04/2027 |
| 59651-137-30 | 2.5 mg | 30's HDPE Container | NB0224001B | 04/2027 |



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