AUROBINDO
Committed to healthier life!
www.AurobindoUSA.com

59651-00266-01000337
SMITH DRUG HDQ
9098 FAIRFOREST RD
PO BOX 1779
SPARTANBURG, SC 29301

March 18, 2020

URGENT DRUG RECALL

Oxycodone and Acetaminophen Tablets 10/325mg
Batch 046180056A

Dear Valued Customer:

This is to inform you of a product recall involving:

NDC	Product Description	Lot Number	Exp Date
13107-046-01	Oxycodone and Acetaminophen Tablets 10/325mg	046180056A	05/2020

Oxycodone and Acetaminophen Tablets are indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

The affected batches can be identified by checking the product name and batch number on the respective product labeling. **See enclosed product label for ease in identifying the product.**

This recall has been initiated because this batch was manufactured in a processing area in which water leakage was observed. Although there was no direct contact of any component with the subject water during the leakage events, the subject batches are being recalled out of an abundance of caution. No other Oxycodone and Acetaminophen batches are affected.

Aurobindo began shipping this batch to customers nationwide April 10, 2019 through May 8, 2019.

Immediately examine your inventory and quarantine the product batch subject to this recall.

This recall is being carried out to the Retail level. Your assistance is appreciated.

Recall Instructions:
Please perform the following activities:

- Immediately examine your inventory and quarantine the specified lots of Oxycodone and Acetaminophen Tablets 10/325mg
- Immediately discontinue distribution of the specific lots being recalled
- Promptly complete the business response form even if you have no product to return.

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

AUROBINDO
Committed to healthier lives
www.AurobindoUSA.com

59651-00266-01000337
SMITH DRUG HDQ
9098 FAIRFOREST RD
PO BOX 1779
SPARTANBURG, SC 29301

Business response forms may be completed by one of the following methods:

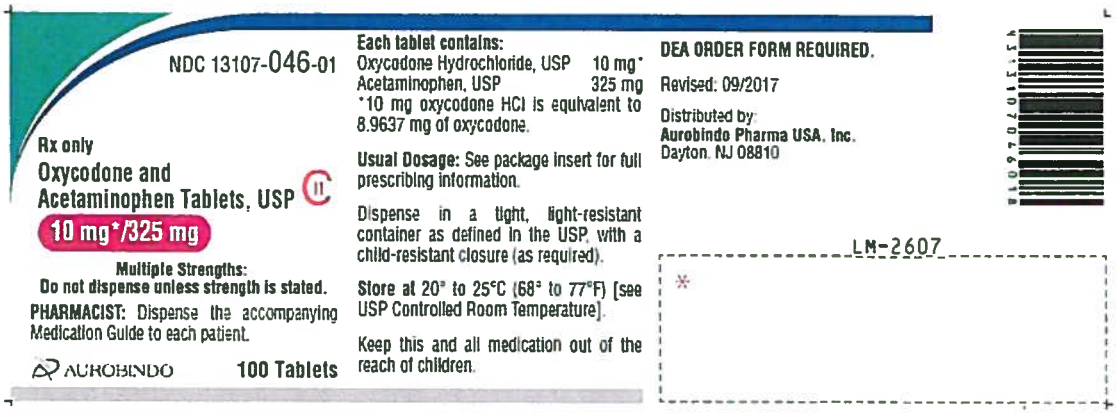
- E-Mail to recall@qualanex.com
- Fax to 847-737-3719
- Mail to:
  Aurobindo USA C/O Qualanex
  1410 Harris Rd
  Libertyville, IL 60048

Please complete and return the enclosed response form as soon as possible. If you need assistance in returning your product or have questions about the recall process, contact Qualanex at 800-505-9291 during the hours of 7:00am to 4:00pm CST. If you have Customer Service related questions, please contact Aurobindo Customer Service at **866-850-2876 Option 1.**

Once the business response form is received by Qualanex, a Return Goods Authorization will be sent to you. Appropriate reimbursement for product returns will be issued upon receipt of the recalled product with the Return Goods Authorization form.

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

Daniel Martins
Senior Vice President, Quality Compliance
279 Princeton Hightstown Road
East Windsor, NJ 08520
dmartins@aurobindousa.com
Direct 732.823.9021


NDC 13107-046-01

Rx only
Oxycodone and Acetaminophen Tablets, USP C II
10 mg*/325 mg

Multiple Strengths:
Do not dispense unless strength is stated.
PHARMACIST: Dispense the accompanying Medication Guide to each patient.

AUROBINDO 100 Tablets

Each tablet contains:
Oxycodone Hydrochloride, USP 10 mg*
Acetaminophen, USP 325 mg
*10 mg oxycodone HCl is equivalent to 8.9637 mg of oxycodone.

Usual Dosage: See package insert for full prescribing information.

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Keep this and all medication out of the reach of children.

DEA ORDER FORM REQUIRED.

Revised: 09/2017

Distributed by:
Aurobindo Pharma USA, Inc.
Dayton, NJ 08810

LM-2607

59651-00266-01000337
SMITH DRUG HDQ
9098 FAIRFOREST RD
PO BOX 1779
SPARTANBURG, SC 29301

AUROBINDO
Committed to healthier lifes
www.AurobindoUSA.com

BUSINESS RESPONSE FORM

Oxycodone and Acetaminophen Tablets 10/325mg Batch 046180056A

Product Recall – March 18, 2020

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the withdrawal 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: _____

Contact Signature _____ Date_____

I have checked my stock and:

_____Do not have any stock of the withdrawn **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. Please return product using enclosed return label.

Item Description	NDC	Lot #	Sealed Qty To Be Returned	Open Qty To Be Returned
Oxycodone and Acetaminophen Tablets 10/325mg	13107-046-01	046180056A		

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 800-505-9291 Office hours 7am to 4pm CST Mon thru Fri.

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