

March 18, 2020

URGENT DRUG RECALL

Acetaminophen and Codeine Tablets USP 300mg/15mg, 300mg/30mg and 300mg/60mg Tablets

Dear Valued Customer:

This is to inform you of a product recall involving:

NDC	Product Description	Lot Number	Exp Date
13107-0058-01	Acetaminophen and Codeine Tablets USP 300/15mg Tablets	058180015A	07/2021
		058180016A	07/2021
		05818017B1	09/2021
13107-0059-99	Acetaminophen and Codeine Tablets USP 300/30mg Tablets	059180023A	05/2021
		059180024A	05/2021
		059180025A	05/2021
13107-0060-01	Acetaminophen and Codeine Tablets USP 300/60mg Tablets	060180017A	06/2021
		060180019B1	06/2021
		060180020A	06/2021
		060180021A	06/2021

Acetaminophen and Codeine phosphate tablets are indicated for the management of mild to moderate pain where treatment with an opioid is appropriate 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 the subject batches were manufactured utilizing a ‘new manufacturing process ‘that was not adequately validated to the expectations of current best industry practices.’ Although the subject batches are expected to remain within specification throughout their labeled shelf life, (and do not appear to pose any risk to the patient), the subject batches are being recalled solely out of an abundance of caution. No other Acetaminophen and Codeine batches are affected.

To date, Aurobindo has not received reports of any adverse events or identifiable safety concerns attributed to this deficiency.

Aurobindo began shipping these batches to customers nationwide July 11, 2018 through June 19, 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 Acetaminophen and Codeine 300/15mg, 300/30mg and 300/60mg.
- Immediately discontinue distribution of the specific lots being recalled
- Promptly complete the business response form even if you have no product to return.

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 13107-058-01

Rx only
Acetaminophen and Codeine Phosphate Tablets, USP 
300 mg/15 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

AUROBINDO 100 Tablets

Each tablet contains:
Acetaminophen, USP 300 mg
Codeine Phosphate, USP 15 mg

Usual Dosage: See Package Insert for complete prescribing information.

Protect from moisture. Dispense in a tight, light-resistant container as described in the USP, with a child-resistant closure. **PROTECT FROM LIGHT.**

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.

Revised: 04/2017


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

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LM-2265

← Unwinding Direction

NDC 13107-059-99

Rx only
Acetaminophen and Codeine Phosphate Tablets, USP 
300 mg/30 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

AUROBINDO 1,000 Tablets

Each tablet contains:
Acetaminophen, USP 300 mg
Codeine Phosphate, USP 30 mg

Usual Dosage: See Package Insert for complete prescribing information.

Protect from moisture. Dispense in a tight, light-resistant container as described in the USP, with a child-resistant closure. **PROTECT FROM LIGHT.**

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.


Revised: 04/2017

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

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LM-2266

NDC 13107-060-01

Rx only
Acetaminophen and Codeine Phosphate Tablets, USP 
300 mg/60 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

AUROBINDO 100 Tablets

Each tablet contains:
Acetaminophen, USP 300 mg
Codeine Phosphate, USP 60 mg

Usual Dosage: See Package Insert for complete prescribing information.

Protect from moisture. Dispense in a tight, light-resistant container as described in the USP, with a child-resistant closure. **PROTECT FROM LIGHT.**

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.

Revised: 04/2017

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

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LM-2268

RECALL STOCK RESPONSE FORM

Acetaminophen and Codeine Tablets USP 300mg/15mg, 300mg/30mg and 300mg/60mg Tablets 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 Signature _____ Date _____

I have checked my stock and:

_____ Do not have any stock of the 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. Please return product using enclosed return label.

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 1-800-505-9291. Office hours 7am to 4pm CST Mon thru Fri.

**Please fax this form to: 1-847-737-3719 or E-mail
recall@qualanex.com**

59651-00269-01124586
 SMITH DRUG CO. DIV. JM SMITH CORP.
 9098 FAIRFOREST RD
 SPARTANBURG, SC 29301-1134



NDC	Name and strength	Lot number	Sealed Quantity to be returned	Open Quantity to be returned
13107-0058-01	Acetaminophen and Codeine Tablets USP 300/15mg	058180015A		
13107-0058-01	Acetaminophen and Codeine Tablets USP 300/15mg	058180016A		
13107-0058-01	Acetaminophen and Codeine Tablets USP 300/15mg	05818017B1		
13107-0059-99	Acetaminophen and Codeine Tablets USP 300/30mg Tablets	059180023A		
13107-0059-99	Acetaminophen and Codeine Tablets USP 300/30mg Tablets	059180024A		
13107-0059-99	Acetaminophen and Codeine Tablets USP 300/30mg Tablets	059180025A		
13107-0060-01	Acetaminophen and Codeine Tablets USP 300/60mg Tablets	060180017A		
13107-0060-01	Acetaminophen and Codeine Tablets USP 300/60mg Tablets	060180019B1		
13107-0060-01	Acetaminophen and Codeine Tablets USP 300/60mg Tablets	060180020A		
13107-0060-01	Acetaminophen and Codeine Tablets USP 300/60mg Tablets	060180021A		