



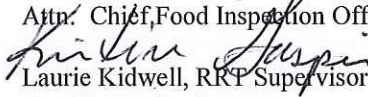
**Indiana State
Department of Health**
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: November 25, 2014

TO: All Local Health Departments
Attn: Chief, Food Inspection Officer

FROM: 
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Aurobindo Pharma USA – RECALL [Drug]

**AFFECTED
PRODUCT:** Gabapentin Capsules, USP 300 mg

SUMMARY: Unclassified Recall; The recall has been initiated because the product lot has been found to contain some empty capsules.

Gabapentin is used as in the treatment of epilepsy and for the management of postherpetic neuralgia (pain after shingles). The affected Gabapentin lot is GESB14011-A, Expiration 12/2015 and is packaged in 100-count bottles, NDC 16714-662-01. The product can be identified by the imprint D on yellow cap and 03 on yellow body with black edible ink.

Product was distributed through Northstar label to retail outlets nationwide.

**SUGGESTED
ACTION:** For consumer inquiry only. Consumers with questions regarding this recall can contact Aurobindo Pharma USA Pharmacovigilance group at (732) 839-9400 Option 2 or PVG@aurobindousa.com Monday through Friday, 8:30AM to 5:00PM EST.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Aurobindo Pharma USA, Inc. Issues Voluntary Nationwide Recall of Northstar Label Gabapentin Capsules, USP 300 mg Due to Complaints of Empty Capsules

Contact:
Consumer:
(732) 839-9400



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

FOR IMMEDIATE RELEASE — November 21, 2014 – Dayton, NJ, Aurobindo Pharma USA is voluntarily recalling lot GESB14011-A of Gabapentin Capsules, USP 300 mg 100-count bottles to the consumer level. The product lot has been found to contain some empty capsules.

Empty capsules could result in missed dose(s) of gabapentin resulting in adverse health consequences that could range from no effect, short term reduction in efficacy, short term withdrawal effect, or status epilepticus (long period seizures) that could be life-threatening. Aurobindo Pharma USA, Inc. has not received any reports of adverse events related to this recall to date, but has received four complaints for empty capsules.

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Aurobindo Pharma USA, Inc. is notifying its distributors and customers by recall letters and is arranging for return of all recalled product. Consumers, distributors, and retailers that have product which is being recalled should stop using, distributing, or dispensing the affected lot and return to place of purchase.

Consumers with questions regarding this recall can contact Aurobindo Pharma USA Pharmacovigilance group at (732) 839-9400 Option 2 or PVG@aurobindousa.com Monday through Friday, 8:30AM to 5:00PM EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

*Aurobindo Pharma USA, Inc. Issues
Voluntary Nationwide Recall of Northstar
Label Gabapentin Capsules, USP 300 mg
Due to Complaints of Empty Capsules
Photo*

NDC 16714-662-01

Rx only

Gabapentin Capsules, USP
300 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

100 Capsules

NORTHSTAR_x

Each capsule contains:
300 mg of gabapentin USP.

Usual Dosage: See package insert for full prescribing information.

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

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Manufactured for: Northstar Rx LLC
Memphis, TN 38141
Toll Free: 1-800-206-7821

Manufactured by: Autobindo Pharma Limited
Unit-VII (SEZ)
Mahabub Nagar (Dt)
AP-509302, INDIA

M.L.No.: 22/MN/AP/2009/T/G



Revised: 08/2011
P1408614

