CardinalHealth

TO: Cust # 633937
P.O.BOX 382367 AP, PHARM
MT AUBURN HOSPITAL-
CAROUSEL
330 MT AUBURN STREET
CAMBRIDGE, MA 02238

FROM: CARDINAL HEALTH
PHARMACEUTICAL DISTRIBUTION
11 CENTENNIAL DRIVE
PEABODY, MA 019607901
FAX: 1-978-532-6916

URGENT PRODUCT RECALL

01/19/2017

RE: CARDINAL HEALTH NOTICE #102224

Dear Valued Customer:

According to our records you have purchased an item that has been recalled or withdrawn by the vendor. Please examine your stock to determine if you have the following product(s) with the affected lot number(s) in your possession. See below for the product disposition instructions established by the vendor. If you have any questions, please contact Cardinal Health Customer Service.

Vendor: VistaPharm

Event: Recall

Class: Unclassified

Level: Retail

Return Product To: PharmaLink, contact at 800-257-3527

Reason: This recall is being initiated because the purified water used to manufacture the drug products may have been contaminated with the bacteria, Burkholderia cepacia. Customers must contact PharmaLink at 800-257-3527 to obtain return instructions.

RETAIL CHAINS: PLEASE FOLLOW YOUR STANDARD CORPORATE POLICY FOR RECALLED AND WITHDRAWN ITEMS

By acknowledging this recall or withdrawal on behalf of my organization, I explicitly agree to and state the following

- I have the authority to respond to or receive product recalls and withdrawal notices on behalf of my organization.
- I have read and understand the instructions for properly handling this recall or withdrawal.
- Our organization agrees to promptly examine all product associated with this recall or withdrawal and check for any affected product.
- Our organization agrees to follow the instructions for handling of the product affected by this product recall or withdrawal.

- Our organization will follow existing Cardinal Health return goods policies and practices, including the following:
  1. Return Authorization (using return code 60) must accompany product being returned in order to receive credit.
  2. Partials of recalled/withdrawn Controlled Substances must be returned directly to the Vendor to receive credit.
  3. Partials of less than 25 percent of the original package quantity will not receive credit from Cardinal Health.
- Our organization agrees to electronically acknowledge the receipt of a recall or withdrawal notification, if this notification is received electronically via this system from Cardinal Health.
- Our organization agrees that if a hard copy notification is received from Cardinal Health, a signed hard copy acknowledgment is required to be returned to Cardinal Health.

Items Affected:

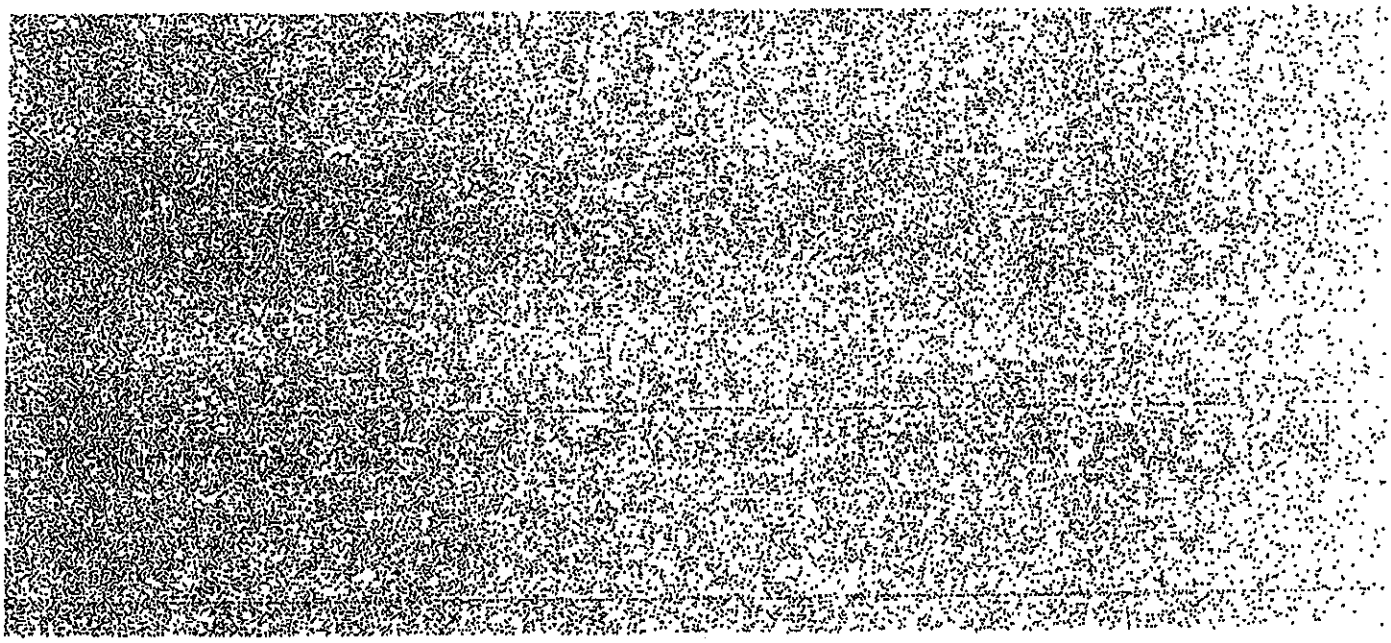
NDC : 66689003650

CARDINAL HEALTH

ITEM NUMBER	PRODUCT DESCRIPTION
4306031	PHENYTOIN SS 100MG/4ML 50X4MLUD

Lot Number(s):

404300 416000 421000 426500



RETAIL LEVEL RECALL

1/20/17

Dear Member,

This is to inform you that VistaPharm, Inc. is issuing a voluntary recall for the products listed to the retail level. Please refer to the following list for the effected products and lot numbers.

These lots are being recalled because the purified water used to manufacture the drug products may have been contaminated with the bacteria, Burkholderia cepacia. Adverse events following the ingestion of a contaminated product could range from no symptoms to potentially life- threatening symptoms. A "normal" healthy person is at less risk of developing any adverse health consequences than is a person with an underlying health condition, such as a patient whose immune system is compromised, a cystic fibrosis patient, or a child with an immature immune system. The products were distributed between 03/2015 and 06/2016. To date, there have been no illnesses associated with the use of these drug products and the testing of the drug products complies with all VistaPharm specifications and during finished goods release testing, the bacteria was not detected.

108-050	66689-008-02	Nystatin Oral Suspension, USP 100,000 units per mL Lot# 422600, 420000, 416100, 417400
108-068	66689-008-16	Nystatin Oral Suspension, USP 100,000 units per mL Lot# 424200, 415500,442900
N/A	66689-023-04	Hydrocodone Bitartrate and Acetaminophen Oral Solution, 7.5mg/325mg per 15 mL C-II Lot# 419000
N/A	66689-023-16	Hydrocodone Bitartrate and Acetaminophen Oral Solution, 7.5mg/325mg per 15 mL C-II Lot # 419800, 429100
N/A	66689-023-50	Hydrocodone Bitartrate and Acetaminophen Oral Solution, 7.5mg/325mg per 15 mL C-II Lot # 418200, 430100, 423800, 413100, 410700
N/A	66689-031-50	Metoclopramide Oral Solution, USP 10 mg/10 mL Lot # 428700, 409500
N/A	66689-036-50	Phenytoin Oral Suspension, USP 100 mg/ 4 mL Lot # 428500, 421000, 418000, 404300
N/A	66689-037-50	Nystatin Oral Suspension, USP 500,000 Units/ 5 mL Lot# 428900, 425600, 421200, 413600, 411500, 417200
N/A	66689-037-99	Nystatin Oral Suspension, USP 500,000 Units/ 5 mL Lot # 429300, 426500, 420600, 417000, 412900, 409900
N/A	66689-038-50	Lactulose Solution, USP 20 g/30 mL 422800 Lot # 430500, 424000, 412500, 405500, 414900
N/A	66689-039-50	Lactulose Solution, USP 10g/15mL 428300 Lot # 423200, 418400, 411100, 406500

N/A	66689-401-50	Oxycodone Hydrochloride Oral Solution, USP 5 mg per 5 mL Lot # 427900, 426700, 424800, 423600, 420800, 416300, 407700, 407300, 405900, 403900
064-642	66689-403-16	Oxycodone Hydrochloride Oral Solution, USP 5 mg per 5 mL Lot # 426900, 404700, 390200
N/A	66689-694-30	Methadone Hydrochloride Oral Concentrate, USP lOmg/mL C-ll Lot # 416600
N/A	66689-694-79	Methadone Hydrochloride Oral Concentrate, USP lOmg/mL C-ll Lot # 449100, 447500, 421800, 418600, 408700, 411900, 413800, 416500, 408500, 389800, 429900, 406300, 406100, 429700, 427300, 427100, 425900
N/A	66689-695-79	Methadone Hydrochloride Oral Concentrate, USP lOmg/mL C-ll (Sugar Free) Lot # 423000, 415100
N/A	66689-711-16	Methadone Hydrochloride Oral Soution, USP 5mg per 5mL C-ll Lot # 388700

With this recall, you are asked to:

- Check your product for the affected lots.
- Stop dispensing and quarantine all impacted product.
- **DO NOT RETURN THIS DRUG TO MUTUAL**
- Contact **PHARMALINK** at **800-257-3527** to arrange return of product
- You may also e-mail at vistapharm@pharmalinkinc.com for call tags
- Contact Brent Slaughter if you have additional questions.