Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 21, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: American Health Packaging – RECALL [Drug]

AFFECTED PRODUCT: **Ibuprofen Tablets, USP, 600 mg, in a hospital unit dose and Oxcarbazepine Tablets, 300 mg.**

SUMMARY: **Unclassified Recall; The recall has been initiated because the product may contain individual blistered doses labeled as Oxcarbazepine Tablets, 300 mg, lot #142544. Mislabeled inner unit dose blister packaging which could result in patients receiving ibuprofen and missing their scheduled dose of oxcarbazepine.**

Cartons of 100 count (10x10) Hospital Unit Dose blisters of AHP Ibuprofen Tablets, USP, 600 mg, with outer carton NDC#: 68084-703-01 and individual dose NDC#: 68084-703-11, Lot #142588, Expiration Date, 01/2016. The drug product can be identified by physical description: white, oval-shaped, film-coated tablets, with "IP 465" printed on one side.

Cartons of 100 count (10x10) Hospital Unit Dose blisters of AHP Oxcarbazepine Tablets, 300 mg, with outer carton NDC#: 62584-143-0 and individual dose NDC#: 62584-143-11, Lot #142544, Expiration Date, 02/2016. The drug product can be identified by physical description: yellow color, capsule shaped, film-coated tablets scored and debossed with '184' on one side and scored on other side.

These hospital unit dose products were distributed nationwide beginning June 20, 2014.

SUGGESTED ACTION: **For consumer inquiry only. Consumers who have received the recalled product should immediately discontinue use and contact GENCO Pharmaceutical Services at 855-419-4608 from 7am to 5pm CST for instructions on returning the recalled product.**

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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.

American Health Packaging Announces the Voluntary Nationwide Recall of Ibuprofen Tablets, USP, 600 mg, 100 Hospital Unit Dose and Oxcarbazepine Tablets, 300 mg, 100 Hospital Unit Dose

Contact:
Consumer:
855-419-4608

Media:
Barbara Brungess
610-727-7199
bbrungess@amerisourcebergen.com

FOR IMMEDIATE RELEASE - July 18, 2014 - American Health Packaging (Columbus, OH) has voluntarily recalled Lot #142588, Expiration Date, 01/2016 of Ibuprofen Tablets, USP, 600 mg, in a hospital unit dose presentation that may contain individual blistered doses labeled as Oxcarbazepine Tablets, 300 mg, lot #142544. In addition, American Health Packaging (AHP) has voluntarily recalled Oxcarbazepine Tablets, 300 mg, lot #142544, Expiration Date, 02/2016. This voluntary recall is the result of mislabeled inner unit dose blister packaging which could result in patients receiving ibuprofen and missing their scheduled dose of oxcarbazepine.

Ibuprofen 600 mg tablets are indicated for the relief of mild to moderate pain; for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis; and treatment of primary dysmenorrhea. Inadvertent consumption of ibuprofen may cause adverse reactions in a number of patients in which use of ibuprofen is contraindicated.

Oxcarbazepine is used for treating certain types of seizures in patients with epilepsy. Failure to receive the proper dose of oxcarbazepine could increase the chances of having a seizure. Affected products as follows:

Cartons of 100 count (10x10) Hospital Unit Dose blisters of AHP Ibuprofen Tablets, USP, 600 mg, with outer carton NDC#: 68084-703-01 and individual dose NDC#: 68084-703-11, Lot #142588, Expiration Date, 01/2016. The drug product can be identified by physical description: white, oval-shaped, film-coated tablets, with “IP 465” printed on one side.

Cartons of 100 count (10x10) Hospital Unit Dose blisters of AHP Oxcarbazepine Tablets, 300 mg, with outer carton NDC#: 62584-143-0 and individual dose NDC#: 62584-143-11, Lot #142544, Expiration Date, 02/2016. The drug product can be identified by physical description: yellow color, capsule shaped, film-coated tablets scored and debossed with '184' on one side and scored on other side.

To date, AHP has received 1 customer complaint which resulted in the investigation and recall of these drug products. AHP has not received any adverse event reports attributable to the mislabeled drug.

American Health Packaging initiated a voluntary product recall on July 1, 2014 as a safety precaution, and will continue to closely monitor for reports of adverse drug reactions and product complaints. Notification of the recall has been sent to distributors who received the affected product with instructions on how to notify their customers.

These hospital unit dose products were distributed nationwide beginning June 20, 2014. No other products or lots were affected by this incident.

Consumers who have received the recalled product should immediately discontinue use and contact GENCO Pharmaceutical Services at 855-419-4608 from 7am to 5pm CST for instructions on returning the recalled product.

For medical information questions or product complaints related to Oxcarbazepine Tablets, 300 mg or Ibuprofen Tablets, USP, 600 mg please contact American Health Packaging customer service at 1-800-707-4621 from 8am to 4pm EST.

Any adverse events that may be related to the use of these products should be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178 or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787 or on the MedWatch website at http://www.fda.gov/safety/medwatch/default.htm.

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

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American Health Packaging Announces the Voluntary Nationwide Recall of Ibuprofen Tablets, USP, 600 mg, 100 Hospital Unit Dose and Oxcarbazepine Tablets, 300 mg, 100 Hospital Unit Dose

Photos

(01) 003 68084 703 11 9

Ibuprofen
Tablet, USP
600 mg

LOT: 142588
EXPIRY: 01/16

American Health
Packaging
Columbus, OH 43217

(01) 003 62584 143 11 8

Oxcarbazepine
Tablet
300 mg

LOT: 142544
EXPIRY: 02/16

American Health
Packaging
Columbus, OH 43217