



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

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 23, 2014

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

FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Contract Packaging Resources - RECALL [Drug]

**AFFECTED
PRODUCT:** Assured™ brand Naproxen Sodium tablets

SUMMARY: Unclassified Recall; The recall of Assured™ brand Naproxen Sodium tablets has been initiated because some cartons actually contain bottles of Ibuprofen, a different pain reliever. The Ibuprofen bottles were placed in the Naproxen Sodium boxes due to a packaging error.

The affected products are: boxes of Assured™ brand Naproxen Sodium Tablets 220mg, 15 count (Lot #FH4102A) [SKU #122368/UPC #639277223685] containing bottles of Ibuprofen softgels in 200mg strength.

The recalled Assured brand drug products were distributed nationwide to Dollar Tree® and sold via the Dollar Tree® retail stores and internet site.

**SUGGESTED
ACTION:** For consumer inquiry only. Consumers may return the recalled products to the place of purchase or contact the firm by phone at 336-252-3422, on Monday – Friday from 8:00 am to 4:00 pm (Eastern).

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.



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.

Contract Packaging Resources, Inc. Issues a Voluntary Nationwide Recall of Assured™ Brand Naproxen Sodium Tablets due to Packaging Mix-Up

Contact

Consumer:
336-252-3422

FOR IMMEDIATE RELEASE - October 20, 2014 - Greensboro, N.C., Contract Packaging Resources, a drug repackaging company, is voluntarily recalling 11,640 boxes of Assured™ brand Naproxen Sodium tablets because some cartons actually contain bottles of Ibuprofen, a different pain reliever. The Ibuprofen bottles were placed in the Naproxen Sodium boxes due to a packaging error. The affected products are: boxes of Assured™ brand Naproxen Sodium Tablets 220mg, 15 count (Lot #FH4102A) [SKU #122368/UPC #639277223685] containing bottles of Ibuprofen softgels in 200mg strength.

Consumers who intentionally avoid using Ibuprofen due to allergy, or other medical conditions, should be advised that they may have inadvertently purchased Ibuprofen 200mg softgels, believing it was Naproxen Sodium 220mg tablets. Allergic reactions can range from mild irritation or hives to serious reactions such as anaphylaxes that may be life-threatening. The firm has not received any reports of adverse events related to this recall.

The recalled Assured brand drug products were distributed nationwide to Dollar Tree® and sold via the Dollar Tree® retail stores and internet site. Contract Packaging Resources is notifying its distributors and customers directly and arranging for replacement of all recalled products. Consumers may return the recalled products to the place of purchase or contact the firm by phone at 336-252-3422, on Monday – Friday from 8:00 am to 4:00 pm (Eastern).

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 preaddressed 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.

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Photo**



