

TYPE: Recall-Packaging Mix-Up

FDA warns of next-day impairment with sleep aid and lowers recommended dose

Drug Name: Assured Brand **Naproxen Sodium Tablets** by: Contract Packaging Resources

Audience: Consumer

Date: **10/22/2014**



ISSUE

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 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, are 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.

BACKGROUND

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

RECOMMENDATION

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).

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.