Endocet (Oxycodone / Acetaminophen) Tablets, (10mg, 325mg) : Recall - Some Bottles Contain Different Strength Tablets

U.S. Food & Drug Administration

ISSUE: Endo Pharmaceuticals and FDA notified pharmacists and patients of a nationwide consumer level recall of Endocet (oxycodone/acetaminophen, USP) Tablets, 10 mg/325 mg because some bottles may contain different strength tablets, resulting in patients taking more than the intended acetaminophen dose. Unintentional administration of tablets with increased acetaminophen content may result in liver toxicity, especially in patients on other acetaminophen containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day.

BACKGROUND: The affected lots were distributed between April 19, 2011 and May 10, 2011 directly to wholesalers who are located in the following states: AL, AZ, CA, CO, NY, OH, ND, PR, IL, KY, NH, NJ, LA, NC, MO, PA, FL and TN. These wholesalers may further distribute to other retailers and wholesalers nationwide. Lot numbers can be found on the side of the manufacturer’s bottle. Tablet descriptions and photographs are provided in the firm's press release.

RECOMMENDATION: Consumers who have the affected product should stop using the product and contact Endo’s agent Stericycle at 1-866-723-2681 for return of the product.

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:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] 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

[06/24/2011 - Press Release [3] - Endo Pharmaceuticals]

SOURCE [4]

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http://www.mdtmag.com/news/2011/06/endocet-oxycodone/acetaminophen-tablets-10mg-325mg-recall-some-bottles-contain-different-strength-tablets

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm260826.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm260979.htm