Endo Pharmaceuticals Opiate Products by Novartis Consumer Health: Public Health Advisory - Potential Safety Risk

U.S. Food & Drug Administration

- Opana ER (oxymorphone hydrochloride) Extended-Release Tablets CII
- Opana (oxymorphone hydrochloride) CII
- Oxymorphone hydrochloride Tablets CII
- PERCOCET (oxycodone hydrochloride and acetaminophen USP) Tablets CII
- PERCODAN (oxycodone hydrochloride and aspirin, USP) Tablets CII
- ENDOCET (oxycodone hydrochloride and acetaminophen USP) Tablets CII
- ENDODAN (oxycodone hydrochloride and aspirin, USP) Tablets CII
- MORPHINE SULFATE Extended-Release Tablets CII
- ZYDONE (hydrocodone bitartrate/acetaminophen tablets, USP) CIII

AUDIENCE: Pharmacy, Consumers

ISSUE: FDA is advising healthcare professionals and patients of a potential problem with opiate products manufactured and packaged for Endo Pharmaceuticals by Novartis Consumer Health at its Lincoln, Nebraska manufacturing site. Due to problems that occurred when these products were packaged and labeled at the site, tablets from one product type may have carried over into packaging of another product. This could result in a stray pill of one medicine ending up in the bottle of another product.

BACKGROUND: Opiates are potent medications used to alleviate pain and are available only by prescription. Endo Pharmaceuticals reports that they are aware of only three product mix-ups with respect to these products since 2009; all three were detected by pharmacists. Endo is not aware of any patient having experienced a confirmed product mix-up, nor any adverse events attributable to a product mix-up.

RECOMMENDATION: FDA advises patients and healthcare professionals to examine opiate medicines made by Endo in their possession and ensure that all tablets are the same.

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

[01/09/20121 - Public Health Advisory [3] - FDA]

SOURCE [4]

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http://www.mdtmag.com/news/2012/01/endo-pharmaceuticals-opiate-products-novartis-consumer-health-public-health-advisory-potential-safety-risk?qt-recent_content=0

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/Drugs/DrugSafety/ucm286226.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm286280.htm