

The FDA is advising patients and healthcare professionals of a potential safety risk associated with certain opiate products manufactured for Endo Pharmaceuticals by Novartis Consumer Health. FDA's inspection of the Novartis manufacturing facility found a packaging problem that may result in a pill, tablet or caplet getting mixed in with a different prescription. The risk of pills ending up in the wrong bottle is a rare event.

FDA is working with Novartis and Endo to resolve the packaging problem. Meanwhile, to ensure patient safety and access to needed pain medicines, patients and healthcare professionals should follow the instructions in the links below to identify whether there is a wrong pill in a medication bottle.

All of the pills in the bottle should look the same. If patients find a pill that is different in shape, size, color, or markings, they should bring their medicine bottle to their pharmacist and not take any of those pills. Patients who have questions should call their pharmacist, healthcare provider, or Endo Pharmaceuticals' call center at 1-800-462-3636.

**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](http://www.fda.gov/MedWatch/report.htm)
- Download form 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

***The following products may be affected:***

- 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

***A visual guide to aid inspection of the affected products is available from Endo Pharmaceuticals at <http://www.endo.com>***

**Reference:**

- Food and Drug Administration (FDA). Certain Opiate Products Made for Endo Pharmaceuticals. Accessed 1/9/2012. Available at: <http://www.fda.gov/Drugs/DrugSafety/ucm286225.htm>
- Endo Pharmaceuticals Visual Guide to Affected Products. Endo Pharmaceuticals, Inc. Accessed 1/9/2012. Available at: [http://www.endo.com/pdf/Supply\\_disruption/Visual\\_Guide.pdf](http://www.endo.com/pdf/Supply_disruption/Visual_Guide.pdf)