



Letter Regarding Possibility of Rare Tablet Mix-Up

January 9, 2012 (revised September 2012)

Dear Pharmacist,

As of September 2012, Endo is aware of several product mix-ups with respect to the following products since 2009, of which all were detected by pharmacists:

Strength	Dosage Strength	NDC
Original Formulation OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	5 mg	63481-907-70
Original Formulation OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	10 mg	63481-674-70
Original Formulation OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	20 mg	63481-617-70
Original Formulation OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	30 mg	63481-571-70
Original Formulation OPANA® ER (oxymorphone hydrochloride) Extended-Release Tablets CII	40 mg	63481-693-70
OPANA® (oxymorphone hydrochloride) Tablets CII	5 mg	63481-612-70
OPANA® (oxymorphone hydrochloride) Tablets CII	10 mg	63481-613-70
Oxymorphone Hydrochloride Tablets CII	5 mg	60951-794-70
Oxymorphone Hydrochloride Tablets CII	10 mg	60951-795-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	2.5/325 mg	63481-627-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	5/325 mg x 100s	63481-623-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	5/325 mg x 500s	63481-623-85
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	7.5/325 mg	63481-628-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	7.5/500 mg	63481-621-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	10/650 mg	63481-622-70
PERCOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	10/325 mg	63481-629-70
PERCODAN® (oxycodone hydrochloride and aspirin, USP) Tablets CII		63481-121-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	7.5/500 mg	60951-796-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	7.5/325 mg	60951-700-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	10/650 mg	60951-797-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	10/325 mg	60951-712-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	5/325mg X 100s	60951-602-70
ENDOCET® (oxycodone hydrochloride and acetaminophen, USP) Tablets CII	5/325mg X 500s	60951-602-85
ENDODAN® (oxycodone hydrochloride and aspirin, USP) Tablets CII		60951-310-70
Morphine Sulfate Extended-Release Tablets CII	15 mg	60951-652-70
Morphine Sulfate Extended-Release Tablets CII	30 mg	60951-653-70
Morphine Sulfate Extended-Release Tablets CII	60 mg	60951-655-70
Morphine Sulfate Extended-Release Tablets CII	100 mg	60951-658-70
Morphine Sulfate Extended-Release Tablets CII	200 mg	60951-659-70
ZYDONE® (hydrocodone bitartrate/acetaminophen tablets, USP) CIII	5 mg	63481-668-70
ZYDONE® (hydrocodone bitartrate/acetaminophen tablets, USP) CIII	7.5 mg	63481-669-70
ZYDONE® (hydrocodone bitartrate/acetaminophen tablets, USP) CIII	10 mg	63481-698-70

We are not aware of any patient having experienced a confirmed product mix-up and there have been no adverse events attributable to a product mix-up. We believe the likelihood of product mix-up reaching a patient is remote.

Endo's principal concern is the health, well-being, and the continuity of care for those patients. In order to minimize the impact of this manufacturing issue on patients and to ensure patients are taking only the product prescribed for them, we recommend that you take the following steps:



- As a precautionary measure and as part of good health practice, ask your patients to confirm that all tablets in their current prescription of any Endo product listed above look alike. Please refer your patients to the visual guide found on www.endo.com so that they can see whether they have the correct medication. A copy of this visual guide is enclosed for your use. If your patient does identify mixed-up tablets, they should promptly consult with you or their pharmacist. Pharmacists have been informed of this issue and are being asked to review tablets as they prepare all new prescriptions of the Endo products listed above.
- For any issue with either product not yet dispensed or product from a patient return, please contact Endo at 1-800-462-3636 for further information.

Please note that we have informed patients if they identify a product mix-up, they should promptly consult with you.

If you have any questions, please contact Endo at 1-800-462-3636.

Sincerely,

A handwritten signature in black ink, appearing to read 'Frank Casty'.

Frank Casty, MD, FACP
Chief Medical Officer, SVP Clinical Development Medical Science

