



Key Purdue Pharma Initiatives to Ensure Appropriate Product Promotion and Prescribing of OxyContin[®] (oxycodone HCl controlled release) Tablets

- **February 2001:** Purdue launched National “Protect Your Practice” campaign, involving direct mail campaign to 395,000 prescribers and 65,000 pharmacists and follow-up visits with sales representatives to heighten awareness among healthcare professionals about diversion and abuse risks.
- **June 2001:** Michael Friedman, President and CEO, sent letters to top OxyContin[®]-prescribing physicians providing a toll-free telephone number to use to report any incidents of improper promotion or unethical conduct by Purdue sales representatives.
- **July 2001:** Purdue voluntarily added amplified warnings about abuse and diversion to product labeling and trained sales representatives to call healthcare professionals’ attention to these warnings.
- **July 2001:** Purdue sent 800,000 letters to healthcare professionals alerting them to the amplified warnings in the OxyContin product labeling .
- **September 2001:** Purdue introduced healthcare law compliance policies that codified principles of appropriate product promotion and prescribing.
- **January 2002:** Purdue established sales re-training objectives for entire sales force to focus on reinforcing the appropriate use of opioids and how to properly identify appropriate patients.
- **November 2003:** Purdue provided refresher training to all field personnel on reporting possible indicators of diversion.
- **April 2004:** Purdue organized corporate compliance function into a single department charged with implementing and monitoring compliance-related matters, and hired an authority on pharmaceutical compliance to head the department and serve as a member of the company’s Executive Committee.
- **July 2004:** Purdue launched quarterly compliance training modules, which test knowledge and comprehension of company policy, laws and regulations, and requires all employees to complete these modules.
- **September 2004:** Purdue required that compliance ratings become part of sales personnel performance evaluations.

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The professional product labeling for OxyContin[®] Tablets contains the following **boxed warning**:

WARNING:

OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 60 mg, 80 mg, and 160 mg Tablets, or a single dose greater than 40 mg, ARE FOR USE IN OPIOID-TOLERANT PATIENTS ONLY. A single dose greater than 40 mg, or total daily doses greater than 80 mg, may cause fatal respiratory depression when administered to patients who are not tolerant to the respiratory depressant effects of opioids.

OxyContin TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

Full prescribing information for OxyContin is available at <http://www.purduepharma.com/PI/Prescription/Oxycontin.pdf>.

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