



July 26, 2010

Dear Prescriber:

Purdue Pharma, L.P. is introducing a Risk Evaluation and Mitigation Strategy (REMS) for OxyContin® (oxycodone HCl controlled-release) Tablets to educate prescribers about the potential abuse, misuse, overdose and addiction from exposure to OxyContin® (oxycodone HCl controlled-release) Tablets.

The goals of the OxyContin® REMS program are:

Goal 1: To inform patients and healthcare professionals about the potential for abuse, misuse, overdose, and addiction of OxyContin®

Goal 2: To inform patients and healthcare professionals about the safe use of OxyContin®.

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 on an as needed (prn) basis.

OxyContin® is not intended for the management of pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. OxyContin® is indicated for postoperative use following the immediate post-operative period only if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate. (See American Pain Society guidelines.) OxyContin® is not indicated for pre-emptive analgesia (preoperative administration for the management of postoperative pain). OxyContin® is not indicated for rectal administration.

OxyContin® contains oxycodone which 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, overdose, and addiction.

OxyContin® Tablets are contraindicated in:

- patients who have significant respiratory depression
- patients who have or are suspected of having paralytic ileus
- patients who have severe bronchial asthma
- patients who have known hypersensitivity to any of its components or the active ingredient, oxycodone

Serious adverse reactions which may be associated with OxyContin® tablet therapy in clinical use are those observed with other opioid analgesics, including respiratory depression, apnea, respiratory arrest, circulatory depression, hypotension, or shock. The most common adverse events (>5%) reported by patients at least once during therapy include constipation, nausea, somnolence, dizziness, pruritus, vomiting, headache, dry mouth, asthenia, and sweating.

*Prescribing and Dispensing*

Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, proper dispensing, and correct storage, handling and disposal are appropriate measures that help to limit the diversion and abuse of opioid drugs. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests is strongly advised.

Prescribing OxyContin® 60 mg or 80 mg Tablets, or a single dose greater than 40 mg, should be reserved only for those patients who have developed tolerance to the sedating and respiratory-depressant effects of opioids. 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 sedating and respiratory depressant effects of opioids. Patients considered opioid tolerant are those who are taking at least: 60 mg oral morphine/day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for *one week or longer*.

The concomitant use of OxyContin® with all cytochrome P450 3A4 inhibitors such as macrolide antibiotics (eg, erythromycin), azole-antifungal agents (eg, ketoconazole), and protease inhibitors (eg, ritonavir) may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse effects and may cause potentially fatal respiratory depression. Patients receiving OxyContin® and a CYP3A4 inhibitor should be carefully monitored for an extended period of time and dosage adjustments should be made if warranted.

When the patient no longer requires therapy with OxyContin® Tablets, doses should be tapered gradually to prevent signs and symptoms of withdrawal in the physically dependent patient.

*Safe Use, Storage and Disposal*

As described in the boxed warning, OxyContin® Tablets are to be swallowed whole and are not to be cut, broken, chewed, crushed, or dissolved. Taking cut, broken, chewed, crushed, or dissolved OxyContin® Tablets leads to rapid release and absorption of a potentially fatal dose of oxycodone.

Compromising the controlled-release delivery system of OxyContin® will result in the uncontrolled delivery of oxycodone and poses a significant risk that could result in overdose and death.

*Misuse and Abuse*

Abuse may occur by taking intact tablets without legitimate purpose, by crushing and chewing or snorting the crushed formulation, or by injecting a solution made from the crushed formulation. The risk of fatal overdose is further increased when oxycodone is abused concurrently with alcohol or other CNS depressants, including other opioids.

*Patient Counseling*

Patients should be counseled about the importance of storing opioid analgesics, including OxyContin®, safely and out of the reach of children, other household members, visitors and pets.

Patients should be instructed against use by individuals other than the patient for whom it was prescribed, as such inappropriate use may have severe medical consequences, including death.

You are strongly advised to discuss the risks associated with OxyContin® with your patients and/or their caregivers and encourage them to read the Medication Guide. This Medication Guide contains important information on the safe and effective use of OxyContin®. In addition to the OxyContin® Full Prescribing Information, we have enclosed a copy of the OxyContin® Medication Guide, which should be provided to patients every time OxyContin® is dispensed.

We are providing you with a packet which contains important information regarding the prescribing of OxyContin®, which we encourage you to review. In addition, the packet contains educational materials that discuss the risk of abuse, misuse, overdose and addiction from exposure to opioids, how to identify patients who are at risk for addiction, and information to counsel patients on proper safe storage of medications. Please complete the OxyContin® Education Confirmation Form and return once you have read the materials. A pre-addressed return envelope is included for your convenience.

**The following items are included in this packet:**

- **OxyContin® Full Prescribing Information**
- **OxyContin® Medication Guide**
- **Prescribing OxyContin® Tablets CII: A Training Guide for Healthcare Providers**
- **OxyContin® Education Confirmation Form**

Please see the attached Full Prescribing Information, including the boxed warning, and the sections specifically addressing overdose with and addiction to OxyContin®.

For more information or to request additional copies of any of these materials, please contact your Purdue Sales Representative or visit us online at [www.oxycontinrems.com](http://www.oxycontinrems.com). In addition, healthcare professionals and patients who have questions about prescribing, dispensing, or taking OxyContin® Tablets should contact the Purdue Medical Services department at (888)726-7535, prompt #1.

Please report any adverse event information associated with the use of OxyContin® Tablets to Purdue Pharma L.P., at (888)726-7535 (prompt #2), or to the FDA MedWatch system by phone at (800)FDA-1088, by fax at (800)FDA-0178, or via the Internet at [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch).

Sincerely,



Craig J. Landau, MD  
Chief Medical Officer