IMPORTANT DRUG WARNING

July 18, 2001

Dear Healthcare Professional,

Reports of illegal misuse, abuse, and diversion of OxyContin® (oxycodone hydrochloride controlled-release) Tablets from various parts of the country have prompted Purdue Pharma L.P. to revise sections of the prescribing information, specifically 1) WARNINGS (including a new Box Warning) which call attention to the potential for misuse, abuse and diversion and 2) INDICATIONS which reinforces the appropriate patient population for whom this product is intended.

OxyContin® is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine. This should be considered when prescribing or dispensing OxyContin® in situations where the prescriber or pharmacist is concerned about an increased risk of misuse, abuse, or diversion. While concerns about abuse, addiction, and diversion should not prevent the proper management of pain, healthcare professionals should be alert to the problems of misuse, abuse, and diversion.

The labeling changes will be implemented within the next several weeks. In the meantime, we want you to be aware of this important safety information. Listed below are highlights of important changes to WARNINGS and INDICATIONS. You should consult the full prescribing information accompanying this letter for all of the changes.

The following BOX WARNING has been added:

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® 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin® (oxycodone hydrochloride controlled-release) TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED OR CRUSHED OxyContin® TABLETS LEADS TO A RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.

This is also reinforced in WARNINGS.

The INDICATIONS AND USAGE section now reads:

> 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® is **NOT** intended for use as a prn analgesic.
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> Physicians should individualize treatment in every case, initiating therapy at the appropriate point along a progression from non-opioid analgesics, such as nonsteroidal anti-inflammatory drugs and acetaminophen, to opioids in a plan of pain management such as outlined by the World Health Organization, the Agency for Health Research and Quality (formerly known as the Agency for Health Care Policy and Research), the Federation of State Medical Boards Model Guidelines, or the American Pain Society.
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> OxyContin® is not indicated for 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 only indicated for postoperative use 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.)

It is important that you forward any adverse event information associated with the use of OxyContin® Tablets to Purdue Pharma L.P. at 1-888-726-7535 (prompt #2). You can also report this information directly to the FDA via the MedWatch system at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail (using a postage-paid form), or the Internet at www.FDA.gov/medwatch.

If you have any questions on how to prevent and detect abuse or diversion of this product, you should contact your State Professional Licensing Board or State Controlled Substances Authority for information.

The abuse and diversion of prescription drugs has become a significant public health issue in the United States. Purdue Pharma L.P. is proud to be the first pharmaceutical manufacturer to voluntarily revise prescribing information for a Schedule II opioid in order to address the issue of abuse and diversion.

Sincerely,

Robert F. Reder, MD
Vice President, Medical Affairs and Worldwide Drug Safety

Enclosure