HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use OxyContin® safely and effectively. See full prescribing information for OxyContin.

OxyContin® (oxycodone hydrochloride controlled-release) Tablets, for oral use, CII
Initial U.S. Approval: 1950

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE
See full prescribing information for complete boxed warning.

- **OxyContin contains oxycodone, a Schedule II controlled substance. Monitor for signs of misuse, abuse, and addiction during OxyContin therapy (5.1, 9).**
- **Fatal respiratory depression may occur, with highest risk at initiation and with dose increases. Instruct patients on proper administration of OxyContin tablets to reduce the risk (5.2).**
- **Accidental ingestion of OxyContin can result in fatal overdose of oxycodone, especially in children (5.3).**

----------RECENT MAJOR CHANGES----------

Boxed Warning	07/2012
Indications and Usage (1)	07/2012
Dosage and Administration (2)	07/2012
Contraindications (4)	07/2012
Warnings and Precautions (5)	07/2012

----------INDICATIONS AND USAGE----------
OxyContin is an opioid agonist product indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. (1)

Limitations of Use

- OxyContin is not for use:
  - As an as-needed (prn) analgesic (1)
  - For pain that is mild or not expected to persist for an extended period of time (1)
  - For acute pain (1)
  - In the immediate postoperative period (1)
  - For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time (1)
- OxyContin 60 mg and 80 mg tablets are only for patients in whom tolerance to an opioid of comparable potency is established. (1)

----------DOSAGE AND ADMINISTRATION----------
- Individualize dosing based on patient's prior analgesic treatment experience, and titrate as needed to provide adequate analgesia and minimize adverse reactions. (2.1, 2.2)
- Do not abruptly discontinue OxyContin in a physically dependent patient. (2.4)
- Tablets must be swallowed intact and are not to be cut, broken, chewed, crushed, or dissolved (risk of potentially fatal dose). (2.5, 5.1)
- OxyContin tablets should be taken one tablet at a time, with enough water to ensure complete swallowing immediately after placing in the mouth. (2.5, 5.9, 17)

----------DOSAGE FORMS AND STRENGTHS----------
- Tablets: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg (3)

----------CONTRAINDICATIONS----------
- Significant respiratory depression (4)
- Acute or severe bronchial asthma (4)
- Known or suspected paralytic ileus and GI obstruction (4)
- Hypersensitivity to oxycodone (4)

----------WARNINGS AND PRECAUTIONS----------
- Elderly, cachectic, and debilitated patients, and patients with chronic pulmonary disease: Monitor closely because of increased risk of respiratory depression. (5.4, 5.5)
- Interaction with CNS depressants: Consider dose reduction of one or both drugs because of additive effects. (5.6, 7.1)
- Hypotensive effects: Monitor during dose initiation and titration (5.7)
- Patients with head injury or increased intracranial pressure: Monitor for sedation and respiratory depression. Avoid use of OxyContin in patients with impaired consciousness or coma susceptible to intracranial effects of CO_2 retention. (5.8)
- Use with caution in patients who have difficulty swallowing or have underlying GI disorders that may predispose them to obstruction. (5.9)
- Concomitant use of CYP3A4 inhibitors may increase opioid effects. (5.14)

----------ADVERSE REACTIONS----------
Most common adverse reactions (>5%) are constipation, nausea, somnolence, dizziness, vomiting, pruritus, headache, dry mouth, asthenia, and sweating. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Purdue Pharma L.P. at 1-888-726-7535 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------
- Muscle relaxants: Avoid use with OxyContin because of increased risk of respiratory depression. (7.2)
- The CYP3A4 isoenzyme plays a major role in the metabolism of OxyContin, drugs that inhibit CYP3A4 activity may cause decreased clearance of oxycodone which could lead to an increase in oxycodone plasma concentrations. (7.3)
- Mixed agonist/antagonist opioid analgesics: Avoid use with OxyContin because they may reduce analgesic effect of OxyContin or precipitate withdrawal symptoms. (7.4)

----------USE IN SPECIFIC POPULATIONS----------
- Nursing mothers: Oxycodone has been detected in human milk. Closely monitor infants of nursing women receiving OxyContin. (8.3)
- Geriatrics: The initial dose may need to be reduced to 1/3 to 1/2 of the usual doses. (8.5)
- Hepatic impairment: Initiate therapy at 1/3 to 1/2 the usual doses and titrate carefully. (8.6)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 07/2012

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

OxyContin® contains oxycodone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit *[see Warnings and Precautions (5.1)]*. Assess each patient's risk for opioid abuse or addiction prior to prescribing OxyContin. The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving OxyContin for signs of misuse, abuse, and addiction during treatment *[see Drug Abuse and Dependence (9)]*.

Life-Threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of OxyContin, even when the drug has been used as recommended and not misused or abused *[see Warnings and Precautions (5.2)]*. Proper dosing and titration are essential and OxyContin should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of OxyContin or following a dose increase. Instruct patients to swallow OxyContin tablets intact. Crushing, dissolving, or chewing the tablet can cause rapid release and absorption of a potentially fatal dose of oxycodone.

Accidental Exposure

Accidental ingestion of OxyContin, especially in children, can result in a fatal overdose of oxycodone *[see Warnings and Precautions (5.3)]*.

1 INDICATIONS AND USAGE

OxyContin is indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

Limitations of Use

OxyContin is not for use:

- As an as-needed (prn) analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- In the immediate postoperative period (the first 24 hours following surgery) for patients not previously taking the drug, because its safety in this setting has not been established.
- For postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.

OxyContin 60 mg and 80 mg tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for patients in whom tolerance to an opioid of comparable potency is established. 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.

2 DOSAGE AND ADMINISTRATION

2.1 Initial Dosing

Initiate the dosing regimen for each patient individually, taking into account the patient's prior analgesic treatment experience. Monitor patients closely for respiratory depression, especially within the first 24-72 hours of initiating therapy with OxyContin *[see Warnings and Precautions (5.2)]*.

Consider the following factors when selecting an initial dose of OxyContin:

- Total daily dose, potency, and any prior opioid the patient has been taking previously;
- Reliability of the relative potency estimate used to calculate the equivalent dose of oxycodone needed (Note: potency estimates may vary with the route of administration);
- Patient's degree of opioid experience and opioid tolerance;
- General condition and medical status of the patient;
- Concurrent medication;
- Type and severity of the patient's pain.

Use of OxyContin as the First Opioid Analgesic

Initiate therapy with 10 mg every 12 hours.

Conversion from other Oral Oxycodone Formulations to OxyContin

Patients receiving other oral oxycodone formulations may be converted to OxyContin by administering one-half of the patient's total daily oral oxycodone dose as OxyContin every 12 hours.

Conversion from other Opioids to OxyContin

While there are useful tables of oral and parenteral equivalents, there is substantial inter-patient variation in the relative potency of different opioid drugs and formulations. Specific recommendations are not available because of a lack of systematic evidence for these types of analgesic substitutions. As such, it is safer to underestimate a patient's 24-hour oral oxycodone requirement and provide rescue medication (e.g., immediate-release oxycodone) than to overestimate and precipitate an adverse reaction. In general, begin with half of the estimated

daily oxycodone requirement as the initial dose, managing inadequate analgesia by supplementation with immediate-release oxycodone.

Published relative potency data are available and may be referred to in clinical practice guidelines such as those published by authorities in the field of pain medicine, but such ratios are approximations. Consider contacting your specific state medical or pharmacy professional societies for further information on how to safely convert patients from one opioid to another.

Conversion from Transdermal Fentanyl to OxyContin

Eighteen hours following the removal of the transdermal fentanyl patch, OxyContin treatment can be initiated. Although there has been no systematic assessment of such conversion, a conservative oxycodone dose, approximately 10 mg every 12 hours of OxyContin, should be initially substituted for each 25 mcg/hr fentanyl transdermal patch. Follow the patient closely during conversion from transdermal fentanyl to OxyContin, as there is limited documented experience with this conversion.

2.2 Titration and Maintenance of Therapy

Individually titrate OxyContin to a dose that provides adequate analgesia and minimizes adverse reactions. Continually reevaluate patients receiving OxyContin to assess the maintenance of pain control and the relative incidence of adverse reactions. During chronic therapy, especially for non-cancer-related pain (or pain associated with other terminal illnesses), periodically reassess the continued need for the use of opioid analgesics.

If the level of pain increases, attempt to identify the source of increased pain, while adjusting the OxyContin dose to decrease the level of pain. Because steady-state plasma concentrations are approximated in 1 day, OxyContin dosage adjustments may be done every 1 to 2 days. Patients who experience breakthrough pain may require dosage adjustment or rescue medication with an appropriate dose of an immediate-release opioid and non-opioid medication.

If signs of excessive opioid-related adverse reactions are observed, the next dose may be reduced. Adjust the dose to obtain an appropriate balance between management of pain and opioid-related adverse reactions.

There are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours. As a guideline, the total daily oxycodone dose usually can be increased by 25% to 50% of the current dose, each time an increase is clinically indicated.

During chronic, around-the-clock opioid therapy, especially for non-cancer pain syndromes, reassess the continued need for around-the-clock opioid therapy regularly (e.g., every 6 to 12 months) as appropriate.

2.3 Patients with Hepatic Impairment

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