

Prescribing

## OxyContin (oxycodone HCl controlled-release) Tablets

### A Training Guide for Healthcare Providers

*Please see Important Safety Information on Page 2 and accompanying Full Prescribing Information, including the Boxed Warning and Medication Guide.*

## IMPORTANT SAFETY INFORMATION

### WARNING: IMPORTANCE OF PROPER PATIENT SELECTION AND POTENTIAL FOR ABUSE

OxyContin contains oxycodone which is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine. (9)

OxyContin 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. (9.2)

OxyContin is a controlled-release oral formulation of oxycodone hydrochloride 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)

OxyContin is not intended for use on an as-needed basis. (1)

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.

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 use in opioid-tolerant patients**, as they may cause fatal respiratory depression when administered to patients who are not tolerant to the respiratory-depressant or sedating effects of opioids. (2.7)

Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. All patients receiving opioids should be routinely monitored for signs of misuse, abuse and addiction. (2.2)

OxyContin **must be swallowed whole and must not 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. (2.1)

The concomitant use of OxyContin with all cytochrome P450 3A4 inhibitors such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole), and protease inhibitors (e.g., 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 (7.2).

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**Please see Important Safety Information on Page 2 and accompanying Full Prescribing Information, including the Boxed Warning and Medication Guide.**

## Introduction

OxyContin is a controlled-release oral formulation of oxycodone hydrochloride 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. It is associated with significant, potentially life-threatening risks, relative to its benefits.

A Risk Evaluation and Mitigation Strategy (REMS) for OxyContin has been created to educate prescribers about the potential risks associated with OxyContin, which are reflected in the goals of the REMS:

**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

The purpose of this training guide is to provide prescribers with important safety information about OxyContin so they can prescribe, dispense and counsel patients appropriately about the potential risk of OxyContin misuse, abuse and addiction.

Selection of patients for treatment with OxyContin should be governed by the same principles that apply to the use of similar opioid analgesics. You should individualize treatment in every case using a progressive plan of pain management such as that outlined by the World Health Organization, the Federation of State Medical Boards Model Policy, and the American Pain Society. Healthcare providers should follow appropriate pain management principles of careful assessment and ongoing monitoring.<sup>1</sup>

In addition, patients and their caregivers must be told to carefully read the OxyContin Medication Guide (included in the accompanying Full Prescribing Information). The Medication Guide contains important information to ensure the safe and appropriate use of OxyContin, and to help prevent misuse, abuse, addiction and overdose.

Finally, it is critical that you counsel patients and their caregivers about the need to store OxyContin out of the reach of children, household visitors and pets in a safe and secure place. This will help reduce the risk of an accidental overdose, which may result in death.

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## Risks of overdose with OxyContin

It is important for all healthcare providers who prescribe opioid analgesics to understand the safety profiles of individual products. Indications and usage for different opioid analgesics vary and the Full Prescribing Information for any specific product should always be consulted before prescribing.

Instruct patients against the use by individuals other than the patient for whom you have prescribed OxyContin, as such inappropriate use may have severe medical consequences, including death.

Following is important information about overdose risks with OxyContin.

### Risk of Overdose from Intact Tablets

Any person who had not developed tolerance to the respiratory depressant or sedating effects of OxyContin is at risk for overdose from exposure to inappropriate doses of OxyContin, especially with concomitant exposure to drugs that depress respiratory drive or consciousness, whether there is a legitimate need for an analgesic or not.

### Risk of Overdose from Alteration of Tablets

**OxyContin Tablets must be swallowed whole and must not be cut, broken, chewed, crushed, or dissolved.** Compromising the controlled-release delivery system will result in the uncontrolled delivery of OxyContin, which could result in overdose and death.<sup>1</sup>

Death due to overdose has occurred in people who chewed or snorted crushed OxyContin Tablets and in people who injected a solution made from crushed tablets. The risk of a fatal overdose is even greater when OxyContin is abused together with alcohol or other CNS depressants, including other opioids.<sup>1</sup>

### Risk of Overdose from Higher Doses

Patients can overdose by taking just one dose of OxyContin.<sup>1</sup>

OxyContin 60 mg and 80 mg Tablets, single doses greater than 40 mg, or total daily doses of 80 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 in patients who are not tolerant to the respiratory depressant effects of opioids.<sup>1</sup>

**Please see Full Prescribing Information for complete details on the dosing and administration of OxyContin.**

## ***Risk of respiratory depression***

Respiratory depression is the most significant serious adverse event risk with OxyContin and can result in death.<sup>1</sup>

This risk is increased in elderly or debilitated patients and following large initial doses in any patient who is not tolerant to the respiratory-depressant or sedating effects of opioid analgesics. Risk is also increased when OxyContin is given together with other agents that depress respiratory drive or consciousness, such as sedatives or hypnotics, general anesthetics, phenothiazines, other tranquilizers, and alcohol.<sup>1</sup>

Even the usual therapeutic doses of OxyContin may decrease respiratory drive to the point of apnea in patients with significant chronic obstructive pulmonary disease or cor pulmonale, substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression.<sup>1</sup> Alternative non-opioid analgesics may need to be considered for these patients.<sup>1</sup>

## ***Additional side effects***

### **Serious Side Effects**

OxyContin may increase the risk of serious adverse reactions such as those observed with other opioid analgesics, including respiratory depression, apnea, respiratory arrest, circulatory depression, hypotension, or shock.<sup>1</sup>

### **Common Side Effects**

The most frequent side effects of OxyContin include constipation, nausea, somnolence, dizziness, vomiting, pruritus, headache, dry mouth, sweating, and asthenia.<sup>1</sup>

Drowsiness, dizziness, or lightheadedness may impair mental and/or physical ability required for the performance of potentially hazardous tasks (eg driving, operating machinery). Patients should be cautioned accordingly.<sup>1</sup>

***Please see accompanying Full Prescribing Information, including the Boxed Warning and Medication Guide.***

## ***Risks of abuse, misuse, and addiction***

### **OxyContin Has an Abuse Liability Similar to Morphine**

OxyContin has been abused by people who chew, snort or inject tablets that have been crushed and/or dissolved. OxyContin abuse has also included taking intact tablets without legitimate purpose. In addition, OxyContin abuse can occur in the absence of addiction and is characterized by taking more OxyContin than prescribed or taking it for non-medical purposes, often in combination with other psychoactive substances.<sup>1</sup>

With parenteral abuse, the tablet excipients can result in death, local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury. Parenteral drug abuse is commonly associated with transmission of infectious diseases, such as hepatitis and HIV<sup>1</sup>.

The risks of misuse and abuse should be considered when prescribing or dispensing OxyContin.<sup>1</sup>

### **Addiction to OxyContin Is Possible**

There is a potential for drug addiction to develop following exposure to OxyContin even during appropriate medical use.<sup>1</sup>

People who have abused prescription medications in the past may have a higher chance of abusing or developing addiction again when prescribed OxyContin. Behaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior. All patients treated with OxyContin require careful monitoring for signs of addiction and drug abuse.<sup>1</sup>

## ***Addictive disorder vs. physical dependence***

It is important to differentiate between a person with an addiction disorder and a patient with pain who is adherent to therapy and has developed a physical dependence on opioid analgesic medications.<sup>1</sup>

### **Patients With Addiction Disorders:<sup>2</sup>**

- Suffer from a chronic, neurobiologic disease with genetic, psychosocial, and environmental components
- Seek a drug in order to quickly affect the “reward center” of their brains

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### Patients With Addiction Disorders:<sup>2</sup> (Continued)

- Crave drugs and use them compulsively
- Continue abuse despite negative, even life-threatening, physical, mental, and/or social consequences
- These persons often develop physical dependence to the substances they are abusing and are, therefore, at risk for signs and symptoms of a withdrawal syndrome upon exposure to an antagonist (in the case of physical dependence on an opioid or benzodiazepine), significant reduction in dose or abrupt cessation of administration of the drug

### Patients With Physical Dependence Who Do Not Have an Addiction Disorder:<sup>2</sup>

- Experience a normal response to the ongoing use of certain medicines, including opioids
- Want sufficient medicine to reach opioid receptors to induce analgesia
- Take medicines to relieve pain—not to satisfy a craving for a psychic effect or to stave off withdrawal syndrome
- Can generally discontinue their medicine with mild to no withdrawal syndrome once their symptoms are gone by gradually tapering the dosage according to their doctor's orders

## Screening for patients at risk for opioid abuse or addiction

Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed an opioid, and all patients receiving opioids should be routinely monitored for signs of misuse, abuse and addiction.<sup>1</sup>

### Patient/Family History<sup>1</sup>

Persons at increased risk for opioid abuse include those with a personal or family history of substance use disorder (including drug or alcohol abuse or addiction) or mental illness (eg, major depression).

Participation or recommended participation in drug abuse treatment programs should be determined. Patients who have undergone opioid detoxification in the past are at higher risk for re-emergence of substance use disorders.

### Screening Tests and Physical Appearance

Many drug abuse screening tests have been developed for use in clinical practice, including the CAGE and CAGE-AID Questionnaire, the Addiction Behaviors Checklist, the Opioid Risk Tool, The Brief MAST, and the Two-Item Conjoint Screening (TICS) for Alcohol & Other Drug Problems.<sup>3-5</sup>

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Physical screening may reveal signs of possible drug abuse. Initial screening clues may include unkempt appearance, ill-fitting clothes suggestive of weight loss/gain, sniffles, watery eyes, cough, nausea; lethargy, drowsiness, and nodding. Careful examination of skin may reveal marks caused by repeated injections.<sup>6,7</sup>

While these signs might suggest abuse, they should not be the only criteria for determining whether opioid abuse has occurred.

### Laboratory Tests

Laboratory signs that may suggest substance abuse include elevated MCV and abnormal liver enzymes.<sup>3-5</sup>

Urine drug testing may yield unexpected results. The use of this technology requires understanding of specificity and sensitivity of the particular analytic method employed. Some point-of-care urine tests for “opioids” or “opiates” do not, for example, detect semisynthetic or synthetic opioid analgesics.<sup>3-5</sup>

All laboratory markers are nonspecific for alcohol or drug use and should be viewed as screens, not as diagnostic criteria.

### Other Signs<sup>1</sup>

Signs of compulsive drug use include covertly obtaining prescription medications from more than one physician, referred to as “Doctor Shopping,” concurrent abuse of related illicit drugs, altering or forging prescriptions, and repeated unsanctioned dose escalations despite warnings.

Other signs of compulsive drug use may be more subtle, including frequent visits to emergency rooms, and hoarding of drugs obtained from routine prescriptions.

### When You Suspect Addiction or Drug Abuse

Following are some suggestions about what to do if you suspect a patient is addicted to or abusing OxyContin:<sup>7</sup>

- Remember, a person abusing drugs or affected by addictive disorder is in need of treatment for that disorder and any concomitant medical or mental conditions they have, although self-administered opioid analgesics may not be indicated
- Refer the patient to an addiction specialist or substance use treatment center, if warranted
- If you are not the primary care physician, always consult a patient's regular physician before initiating treatment with an opioid analgesic
- Contact authorities if you are threatened in any way

## Proper patient selection

**Careful patient selection is key to initiating the appropriate use of OxyContin. The decision to use OxyContin must balance the potential benefits with the risks of OxyContin treatment. The following points should be reviewed when considering OxyContin treatment for your patients.<sup>1</sup>**

### Who May Be Appropriate for Treatment With OxyContin

OxyContin is a controlled-release oral formulation of oxycodone hydrochloride 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.<sup>1</sup>

As used here, “moderate” and “moderate to severe” pain do not include commonplace and ordinary aches and pains, pulled muscles, cramps, sprain, or similar discomfort.

OxyContin is not intended for use on an as-needed (prn) basis.<sup>1</sup>

OxyContin is not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery) because safety during this time frame has not been established.<sup>1</sup>

OxyContin is not indicated for pain during the postoperative period if the pain is mild, or not expected to persist for an extended period of time.<sup>1</sup>

OxyContin is indicated for postoperative use, after the immediate postoperative period, only:<sup>1</sup>

- If the patient has already been 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).<sup>1</sup>

OxyContin is not indicated for preemptive analgesia (administration preoperatively for the management of postoperative pain).<sup>1</sup>

OxyContin is not indicated for rectal administration.<sup>1</sup>

### Some Patients Should Never Receive OxyContin

For some patients, the risks associated with OxyContin therapy outweigh any potential benefits, and therefore, its use is contraindicated in such patient populations.

OxyContin is contraindicated in patients with known hypersensitivity to oxycodone, or in any situation where opioids are contraindicated, including:<sup>1</sup>

- Patients who have significant respiratory depression
- Patients who have or are suspected of having paralytic ileus
- Patients who have acute or severe bronchial asthma

The safety and effectiveness of OxyContin has not been established in pediatric patients below the age of 18 years.<sup>1</sup>

### Assess for Risks of Opioid Abuse or Addiction before Starting Treatment With OxyContin

Patients should be assessed for risks of opioid abuse or addiction before they start treatment with OxyContin. In addition to a complete medical history, a detailed history of alcohol and other substance use in the patient and family is important to establish before initiating treatment with OxyContin.<sup>1,3</sup>

Persons at increased risk for opioid abuse include those with a personal or family history of substance use disorders (including drug or alcohol abuse or addiction) or mental illness (eg, major depression).<sup>1,3</sup>

Documentation and maintenance of careful prescribing and treatment records is essential for supporting the evaluation, the reason for OxyContin prescribing, the overall pain management plan, and any consultations received.<sup>1,3</sup> Documentation should include:

- Name, strength and quantity of the opioid prescribed
- Dose and frequency of administration
- Timeliness of requests for another prescription
- Initial and ongoing assessment of patients' pain
- Proper prescribing practices
- Periodic reevaluation of all therapy prescribed or recommended, including progress toward established treatment goals.

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## Appropriate dosing and administration<sup>1</sup>

OxyContin is available in 7 dosage strengths (10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg tablets) and is to be administered every 12 hours.

**60 mg and 80 mg tablets, single doses of greater than 40 mg, or daily doses greater than 80 mg are for use in opioid-tolerant patients only.**

**Initial doses should be low, especially in patients receiving concurrent treatment with muscle relaxants, sedatives, or other central nervous system (CNS) medications. To avoid the risk of a potentially fatal dose, tablets must be swallowed whole and must not be cut, broken, chewed, crushed, or dissolved.**

### Starting Therapy

Physicians should initiate OxyContin treatment only in patients who are at the appropriate point along the progression from non-opioid analgesics, such as non-steroidal anti-inflammatory drugs and acetaminophen, to opioids, such as OxyContin, in a plan of pain management such as outlined by the World Health Organization, the Federation of State Medical Boards Model Guidelines, or the American Pain Society.<sup>1</sup>

It is critical to initiate and adjust the dosing regimen for each patient individually, taking into account:<sup>1</sup>

- Risk factors for abuse or addiction
- Age, general condition and medical status of the patient
- Current and anticipated pain intensity (eg, stable, increasing, decreasing)
- Patient's opioid exposure and degree of opioid tolerance (if any)
- Special instructions for patients who are not opioid tolerant
- Major organ function that may affect absorption, distribution, metabolism or excretion of OxyContin
- Pharmacokinetic and pharmacodynamic interactions with concomitant medications
- Incomplete cross-tolerance among opioid analgesics
- Genetic variability in pharmacokinetics or pharmacodynamics
- Balance between pain control and adverse reactions of OxyContin

### For patients who are new to opioid therapy

Experience indicates a reasonable starting dose of OxyContin for patients who are taking non-opioid analgesics and require continuous around-the-clock therapy for an extended period of time is 10 mg every 12 hours.

**Please see Important Safety Information on Page 2 and accompanying Full Prescribing Information, including the Boxed Warning and Medication Guide.**

### For patients who are NOT opioid-tolerant

Use low initial doses, especially in patients who are receiving concurrent treatment with muscle relaxants, sedatives, or other CNS medications.

Do not begin treatment with 60 mg or 80 mg tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg, as these doses may cause fatal respiratory depression.

### For patients previously taking opioids<sup>1</sup>

See Full Prescribing Information for full details on converting from existing opioid therapy to OxyContin and for operational criteria for opioid tolerance.

### Monitoring Effects of Concomitant Exposure to CYP3A4 Inhibitors and Inducers<sup>1</sup>

Since the CYP3A4 isoenzyme plays a major role in the metabolism of OxyContin, drugs that alter CYP3A4 activity may cause changes in clearance of oxycodone which could lead to changes in oxycodone plasma concentrations.

The expected clinical results with CYP3A4 inhibitors would be an increase in oxycodone plasma concentrations and possibly increased or prolonged opioid effects. The expected clinical results with CYP3A4 inducers would be a decrease in oxycodone plasma concentrations, lack of efficacy or, possibly, development of an abstinence syndrome in a patient who had developed physical dependence to oxycodone.

If co-administration is necessary, caution is advised when initiating OxyContin treatment in patients currently taking, or discontinuing, CYP3A4 inhibitors or inducers. It is important to evaluate these patients at frequent intervals and consider dose adjustments until stable drug effects are achieved.

### Individualizing Dosage<sup>1</sup>

After therapy is initiated, individually titrate OxyContin to a dose that provides an appropriate balance between pain relief and opioid-related side effects.

- Patients who experience breakthrough pain may need dosage adjustment or rescue medication
- OxyContin dose adjustments may be made every 1-2 days
- The 12-hour dosing interval should not be changed; it is most appropriate to increase the q12h dose, if analgesic goals are not being met and it is anticipated that side effects can be managed.
- The total daily dose can usually be increased by 25% to 50% of the current dose
- If significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration, if appropriate

During periods of changing analgesic requirements, including initial titration, maintain frequent communication with other members of the healthcare team, your patient, and the caregiver/family.

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## Appropriate dosing and administration (Continued)

### Continuing Therapy

During chronic opioid therapy, especially for non-cancer pain syndromes, the continued need for around-the-clock opioid therapy should be reassessed periodically (eg, every 6 to 12 months) as appropriate.<sup>1</sup>

OxyContin therapy should be reviewed and adjusted, taking into consideration the patient's own reports of pain and side effects and the health care provider's clinical judgment. OxyContin should be individually titrated to a dose that provides an appropriate balance between analgesia and side effects. All patients treated with OxyContin should be routinely monitored for signs of misuse, abuse, and addiction.<sup>1</sup>

### Stopping Therapy

When the patient no longer requires therapy with OxyContin, taper the dose gradually to prevent signs and symptoms of withdrawal in the physically-dependent patient.

Please see Important Safety Information on Page 2 and accompanying Full Prescribing Information, including Boxed Warning and Medication Guide.

## What you need to tell patients about OxyContin

Once you have identified an appropriate patient for OxyContin treatment, it is important to discuss the following information with the patient and/or their caregiver to ensure safe and appropriate use and disposal, and help to prevent misuse, abuse, and risk of overdose.

- **Patients and caregivers must be told to carefully read the OxyContin Medication Guide that is provided with each OxyContin prescription. It is extremely important to remind them that the important safety information in the Medication Guide could have changed since their last OxyContin prescription was filled.**
- Patients and caregivers should be told that since OxyContin first became available, there have been reports of misuse, overdose, abuse, and addiction in some people, so the patient needs to decide if he or she wants to use, or continue to use OxyContin.<sup>1</sup>
- **Also tell patients and caregivers:**
  1. Always follow the prescribing directions about OxyContin *exactly* and never change the dose, the dosing frequency, or suddenly stop taking OxyContin without consulting the doctor first.<sup>1</sup>

**Please see Important Safety Information on Page 2 and accompanying Full Prescribing Information, including the Boxed Warning and Medication Guide.**

2. Take OxyContin only by mouth and swallow the tablets whole. Do not break, crush, dissolve, or chew them before swallowing as this can be very dangerous, causing an overdose, and possibly death.<sup>1</sup>
  3. OxyContin is an opioid. You should only take doses more than 40 mg at one time if you have already been taking opioids and your prescribing doctor has said it is okay.<sup>1</sup>
  4. OxyContin may impair mental and/or physical ability required to perform potentially hazardous tasks (eg, driving, operating heavy machinery).
  5. You should not combine OxyContin with alcohol or other central nervous system depressants (eg, sedatives, hypnotics) because dangerous additive effects may occur, resulting in serious injury or death.
  6. Women of childbearing potential who become, or are planning to become, pregnant should consult their doctor regarding the effects of analgesics and other drug use during pregnancy on themselves and their unborn child.
  7. Keep OxyContin away from children, household visitors and pets in a safe and secure place, such as locked box or cabinet. Accidental overdose by a child is dangerous and may result in death.
  8. OxyContin and other opioid analgesics should not be stored in the bathroom medicine cabinet because bathroom medicine cabinets rarely lock, in the glove compartment of a car or in kitchen cabinets, inside purses, coat pockets, nightstands, or other locations easily accessed by others.<sup>1</sup>
  9. OxyContin contains a drug that some people may want to abuse. OxyContin should only be used by the patient who was prescribed OxyContin. A patient should protect his or her OxyContin from being stolen.<sup>1</sup>
  10. Giving or selling OxyContin to other people is very dangerous and against the law.<sup>1</sup>
  11. When OxyContin is no longer needed, patients should flush unused tablets down the toilet.<sup>1</sup> OxyContin Tablets and other opioid analgesics should not be discarded in the wastebasket where children or others can find them.
  12. If a patient suspects that someone has stolen their OxyContin, he or she should report to the local police department.<sup>1</sup>
  13. Never take or give medicine in the dark. Patients should always turn the light on and wear their glasses if they need them for reading before taking or administering medication.
  14. Use child-resistant packaging on medicines whenever possible.
- Caregivers should be told to check the label every time they give medicine to a loved one.

This guide for healthcare providers was written to support the REMS for OxyContin. For more information, please see the accompanying Full Prescribing Information and visit [www.oxycontinrems.com](http://www.oxycontinrems.com).

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