

## MEDICATION GUIDE

### **OXYCONTIN<sup>®</sup> (ox-e-KON-tin) (CII)** **(oxycodone hydrochloride controlled-release)** **Tablets**

Read this Medication Guide before you start taking OxyContin and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

#### **What is the most important information I should know about OxyContin?**

- **OxyContin can cause serious side effects, including addiction or death.**
- **Do not cut, break, chew, crush, or dissolve OxyContin before swallowing. If OxyContin is taken in this way, the medicine in the tablets will be released too fast. This is dangerous. It may cause you to stop breathing, and may lead to death.**
- OxyContin is not for use to treat pain that you only have once in a while (“as needed”).
- **Do not take OxyContin 60 mg or 80 mg tablets unless you are “opioid tolerant.”** Opioid tolerant means that you regularly use OxyContin or another opioid medicine for your constant (around-the-clock) pain and your body is used to it.
- **Do not take more than 40 mg of OxyContin in one dose or more than 80 mg of OxyContin in one day unless you are “opioid tolerant.”** This may cause you to stop breathing and may lead to death.

- **OxyContin is a federally controlled substance (CII)** because it is a strong opioid pain medicine that can be abused by people who abuse prescription medicines or street drugs.

- **Prevent theft, misuse and abuse.** Keep OxyContin in a safe place, to keep it from being stolen. OxyContin can be a target for people who misuse or abuse prescription medicines or street drugs.

- **Never give OxyContin to anyone else, even if they have the same symptoms you have. It may harm them and even cause death.**

- Before taking OxyContin, tell your doctor if you or a family member have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental illness.

- **Do not drink alcohol while using OxyContin. Using alcohol with OxyContin may increase your risk of dangerous side effects, including death.**
- **Certain medicines can interact with OxyContin and cause you to have high levels of oxycodone in your blood. This may cause you to stop breathing and lead to death. Before taking OxyContin, tell your healthcare provider if you take an antibiotic, an antifungal medicine, or an anti-HIV medicine.**

### **What is OxyContin?**

- OxyContin is a prescription medicine used when an opioid medicine is needed to manage moderate to severe pain that continues around-the-clock and is expected to last for a long period of time.
- It is not known if OxyContin is safe and effective in children younger than 18 years.
- OxyContin is not for use:
  - to manage pain “as needed”
  - before surgery to manage any pain from your surgery
  - to manage pain after surgery if the pain is mild and is not expected to last for a long period of time
- If you already take OxyContin, it may be used to manage your pain after surgery if:
  - it has been at least 12 to 24 hours after your surgery, and
  - your pain from surgery is expected to be moderate to severe, and last for a long period of time.

### **Who should not take OxyContin? Do not take OxyContin if you:**

- are allergic to any of its ingredients. See the end of this Medication Guide for a list of the ingredients in OxyContin.
- have had a severe allergic reaction to a medicine that contains oxycodone. Ask your healthcare provider if you are not sure.
- are having an asthma attack or have severe asthma, trouble breathing, or lung problems
- have a bowel blockage called paralytic ileus

## **What should I tell my healthcare provider before taking OxyContin?**

**OxyContin may not be right for you. Before taking OxyContin, tell your doctor if you:**

- have trouble breathing or lung problems
- have had a head injury
- have liver or kidney problems
- have adrenal gland problems, such as Addison's disease
- have severe scoliosis that affects your breathing
- have thyroid problems
- have enlargement of your prostate or a urethral stricture
- have or had convulsions or seizures
- have a past or present drinking problem or alcoholism
- have hallucinations or other severe mental problems
- have past or present substance abuse or drug addiction
- have any other medical conditions
- are pregnant or plan to become pregnant. If you take OxyContin regularly before your baby is born, your newborn baby may have signs of withdrawal because their body has become used to the medicine. Signs of withdrawal in a newborn baby can include:
  - irritability
  - crying more than usual
  - shaking (tremors)
  - jitteriness
  - breathing faster than normal
  - diarrhea or more stools than normal
  - sneezing
  - yawning
  - vomiting
  - fever

If you take OxyContin right before your baby is born, your baby could have breathing problems at birth.

- are breast-feeding. You should not take OxyContin if you are nursing. Some oxycodone from OxyContin passes into breast milk. A nursing baby could become very drowsy or have difficulty breathing or feeding well.

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Sometimes the doses of medicines that you take with OxyContin may need to be changed if used together.

- **See “What is the most important information I should know about OxyContin?”**
- Be especially careful about taking other medicines that make you sleepy such as: pain medicines
  - sleeping pills
  - anxiety medicines
  - antihistamines
  - anti-depressants
  - tranquilizers
  - anti-nausea medicine

Do not take other medicines without talking to your healthcare provider. Your healthcare provider will tell you if it is safe to take other medicines while you take OxyContin.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist.

### **How should I take OxyContin?**

- See “What is the most important information I should know about OxyContin?”
- **Take OxyContin exactly as prescribed. Do not change your dose unless your healthcare provider tells you to.**
- **Swallow OxyContin tablets whole. Do not cut, break, chew, crush, or dissolve before swallowing.**
- Take OxyContin every 12 hours
- You can take OxyContin with or without food.
- If you miss a dose, take it as soon as possible. Take your next dose 12 hours later. Do not take more than your prescribed dose of OxyContin. Call your healthcare provider if you are not sure about your dose of OxyContin or when to take it.
- **If you take more OxyContin than prescribed**, or overdose, call your local emergency number (such as 911) or your local Poison Control Center right away, or get emergency help.
- **Talk with your healthcare provider regularly about your pain** to see if you still need to take OxyContin.

## What should I avoid while taking OxyContin?

- **Do not drink alcohol while using OxyContin.** See “What is the most important information I should know about OxyContin?” **Do not drive, operate heavy machinery, or do other dangerous activities, especially when you start taking OxyContin and when your dose is changed, until you know how you react to this medicine. OxyContin can make you sleepy, and also cause you to feel dizzy. Ask your healthcare provider to tell you when it is okay to do these activities.**

## What are the possible side effects of OxyContin?

**OxyContin can cause serious side effects, including:**

- See “What is the most important information I should know about OxyContin?”
- **OxyContin can cause serious breathing problems that can become life-threatening, especially if OxyContin is used the wrong way. Call your healthcare provider or get medical help right away if:**
  - your breathing slows down
  - you have shallow breathing (little chest movement with breathing)
  - you feel faint, dizzy, confused, or
  - you have any other unusual symptoms

These can be signs or symptoms that you have taken too much OxyContin (overdose) or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away.**

- **Central nervous system effects, including sleepiness, dizziness, passing out, becoming unconscious, or coma.**
- **OxyContin may cause a worsening of seizures in people who already have seizures.**
- **OxyContin can cause your blood pressure to drop.** This can make you feel dizzy and faint if you get up too fast from sitting or lying down. Low blood pressure is also more likely to happen if you take other medicines that can also lower your blood pressure. Severe low blood pressure can happen if you lost blood or take certain other medicines.
- **OxyContin can cause physical dependence.** Do not stop taking OxyContin or any other opioid without talking to your healthcare provider about how to slowly stop your medicine. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependence is not the same as drug addiction. Tell your healthcare provider if you have any of these signs or symptoms of withdrawal while slowly stopping OxyContin:
  - feel restless
  - tearing eyes
  - runny nose

- yawning
  - sweating
  - chills or hair on your arms “standing up”
  - muscle aches, backache
  - dilated pupils of your eyes
  - feel irritable or anxious
  - nausea, loss of appetite, vomiting, diarrhea
  - increase in your blood pressure, breathing faster, or your heart beats faster
- **There is a chance of abuse or addiction with OxyContin.** The chance is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.

**The most common side effects of OxyContin include:**

- constipation
- nausea
- drowsiness
- dizziness
- itching
- vomiting
- headache
- dry mouth
- weakness
- sweating

Some of these side effects may decrease with continued use. Talk with your healthcare provider if you continue to have these side effects. These are not all the possible side effects of OxyContin. For a complete list, ask your healthcare provider or pharmacist.

Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids) including OxyContin, and is unlikely to go away without treatment. Talk to your healthcare provider about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking OxyContin.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1 088.

### **How should I store OxyContin?**

- **Keep OxyContin out of the reach of children.** Accidental overdose by a child is dangerous and can lead to death.
- Store OxyContin at 59° F to 86°F (15° C to 30° C)
- Keep OxyContin in the container it comes in.
- Keep the container tightly closed and away from light.
- After you stop taking OxyContin, flush the unused tablets down the toilet.

### **General information about OxyContin**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use OxyContin for a condition for which it was not prescribed. Never give your OxyContin to other people even if they have the same symptoms you have.

### **Selling or giving away OxyContin may harm others, even causing death, and is against the law.**

This Medication Guide summarizes the most important information about OxyContin. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about OxyContin that is written for health professionals. For more information about OxyContin, go to [www.purduepharma.com](http://www.purduepharma.com) or call 1-888-726-7535.

### **What are the ingredients of OxyContin?**

Active ingredient: oxycodone hydrochloride

Inactive ingredients in all strengths: butylated hydroxytoluene (BHT), hypromellose, polyethylene glycol 400, polyethylene oxide, magnesium stearate, titanium dioxide

- The 10 mg tablets also contain: hydroxypropyl cellulose.
- The 15 mg tablets also contain: black iron oxide, yellow iron oxide, and red iron oxide.
- The 20 mg tablets also contain: polysorbate 80 and red iron oxide.
- The 30 mg tablets also contain: polysorbate 80, red iron oxide, yellow iron oxide, and black iron oxide.
- The 40 mg tablets also contain: polysorbate 80 and yellow iron oxide.
- The 60 mg tablets also contain: polysorbate 80, red iron oxide and black iron oxide
- The 80 mg tablets also contain: hydroxypropyl cellulose, yellow iron oxide and FD&C Blue #2/Indigo Carmine Aluminum Lake

**Always check to make sure that the medicine you are taking is the correct one. The dosage strength and appearance of each OxyContin tablet are as follows:**

- 10 mg: white-colored with “OP” on one side and “10” on the other
- 15 mg: gray-colored with “OP” on one side and “15” on the other
- 20 mg: pink-colored with “OP” on one side and “20” on the other

- 30 mg: brown-colored with “OP” on one side and “30” on the other
- 40 mg: yellow-colored with “OP” on one side and “40” on the other
- 60 mg: red-colored with “OP” on one side and “60” on the other
- 80 mg: green-colored with “OP” on one side and “80” on the other

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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