

**Medication Guide****OXYCODONE (OX-ee-KON-dohn) HCI EXTENDED-RELEASE TABLETS, CII****OXYCODONE HCI EXTENDED-RELEASE TABLETS ARE:**

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not for use to treat pain that is not around-the-clock.
- Not for use in children less than 11 years of age and who are not already using opioid pain medicines regularly to manage pain severe enough to require daily around-the-clock long-term treatment of pain with an opioid.

**Important information about OXYCODONE HCI EXTENDED-RELEASE TABLETS:**

- **Get emergency help right away if you take too much OXYCODONE HCI EXTENDED-RELEASE TABLETS (overdose).** When you first start taking OXYCODONE HCI EXTENDED-RELEASE TABLETS, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Taking OXYCODONE HCI EXTENDED-RELEASE TABLETS with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your OXYCODONE HCI EXTENDED-RELEASE TABLETS. They could die from taking it. Selling or giving away OXYCODONE HCI EXTENDED-RELEASE TABLETS is against the law.
- Store OXYCODONE HCI EXTENDED-RELEASE TABLETS securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

**Do not take OXYCODONE HCI EXTENDED-RELEASE TABLETS if you have:**

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

**Before taking OXYCODONE HCI EXTENDED-RELEASE TABLETS, tell your healthcare provider if you have a history of:**

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

**Tell your healthcare provider if you are:**

- **pregnant or planning to become pregnant.** Prolonged use of OXYCODONE HCI EXTENDED-RELEASE TABLETS during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Not recommended during treatment with OXYCODONE HCI EXTENDED-RELEASE TABLETS. It may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking OXYCODONE HCI EXTENDED-RELEASE TABLETS with certain other medicines can cause serious side effects that could lead to death.

**When taking OXYCODONE HCI EXTENDED-RELEASE TABLETS:**

- Do not change your dose. Take OXYCODONE HCI EXTENDED-RELEASE TABLETS exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 12 hours at the same time every day. Do not take more than your prescribed dose in 12 hours. If you miss a dose, take your next dose at your usual time.
- Swallow OXYCODONE HCI EXTENDED-RELEASE TABLETS whole. Do not cut, break, chew, crush, dissolve, snort, or inject OXYCODONE HCI EXTENDED-RELEASE TABLETS because this may cause you to overdose and die.
- OXYCODONE HCI EXTENDED-RELEASE TABLETS should be taken 1 tablet at a time. Do not pre-soak, lick, or wet the tablet before placing in your mouth to avoid choking on the tablet.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking OXYCODONE HCI EXTENDED-RELEASE TABLETS without talking to your healthcare provider.**

**Dispose of expired, unwanted, or unused OXYCODONE HCI EXTENDED-RELEASE TABLETS by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.**

**While taking OXYCODONE HCI EXTENDED-RELEASE TABLETS DO NOT:**

- Drive or operate heavy machinery until you know how OXYCODONE HCI EXTENDED-RELEASE TABLETS affects you. OXYCODONE HCI EXTENDED-RELEASE TABLETS can make you sleepy, dizzy, or lightheaded.
- Drink alcohol, or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with OXYCODONE HCI EXTENDED-RELEASE TABLETS may cause you to overdose and die.

**The possible side effects of OXYCODONE HCI EXTENDED-RELEASE TABLETS are:**

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

**Get emergency medical help if you have:**

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of OXYCODONE HCl EXTENDED-RELEASE TABLETS. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088. **For more information go to [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov)**

Distributed by: KVK-Tech, Inc. Newtown, PA 18940

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

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Distributed by: Marketed by: Rhodes Pharmaceuticals L.P., Coventry, RI 02816 US, <http://rhodespharma.com>, or call 1-888-827-0616

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