

**Medication Guide****ZOHYDRO™ ER (zoh-hye-droh)****(hydrocodone bitartrate) Extended-Release Capsules, CII****ZOHYDRO ER is:**

- A strong, long-acting (extended-release) prescription pain medicine that contains an opioid (narcotic).  
Taking ZOHYDRO ER can cause opioid addiction, abuse, misuse, overdose and death, even if you take your dose correctly as prescribed. Because of this, ZOHYDRO ER is used only to manage pain that is 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.
- Not for use to treat pain that is not around-the-clock.

**Important information about ZOHYDRO ER:**

- Get emergency help right away if you take too much ZOHYDRO ER (overdose). ZOHYDRO ER can cause breathing problems that can lead to death, even if you take your dose as prescribed.
- Never give anyone else your ZOHYDRO ER. They could die from taking it. Store ZOHYDRO ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away ZOHYDRO ER is against the law.

**Do not take ZOHYDRO ER if you have:**

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

**Before taking ZOHYDRO ER, 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.** ZOHYDRO ER may harm your unborn baby. Long-term (chronic) use during pregnancy can cause life-threatening withdrawal symptoms in your newborn baby.
- **breastfeeding.** ZOHYDRO ER passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking ZOHYDRO ER with certain other medicines can cause serious side effects.

**When taking ZOHYDRO ER:**

- Do not change your dose. Take ZOHYDRO ER exactly as prescribed by your healthcare provider.
- 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 the next day.
- Swallow ZOHYDRO ER whole. Do not cut, break, chew, crush, or dissolve ZOHYDRO ER because this may cause you to overdose and die.

**Call your healthcare provider if the dose you are taking does not control your pain.**

- **Do not stop taking ZOHYDRO ER without talking to your healthcare provider.**
- After you stop taking ZOHYDRO ER, flush any unused capsules down the toilet.

**While taking ZOHYDRO ER Do Not:**

- Drive or operate heavy machinery, until you know how ZOHYDRO ER affects you. ZOHYDRO ER 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 ZOHYDRO ER may cause you to overdose and die.

**The possible side effects of ZOHYDRO ER 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, or you are feeling faint.

These are not all the possible side effects of ZOHYDRO ER. 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)**

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

Issue: October 2013