

Medication Guide

ZOHYDRO[®] ER (zoh-hye-droh)

(hydrocodone bitartrate) extended-release capsules, CII

ZOHYDRO ER is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat 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.

Important information about ZOHYDRO ER:

- **Get emergency help right away if you take too much ZOHYDRO ER (overdose).** When you first start taking ZOHYDRO ER, 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 ZOHYDRO ER 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 ZOHYDRO ER. They could die from taking it. Selling or giving away ZOHYDRO ER is against the law.
- Store ZOHYDRO ER securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take ZOHYDRO ER if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or 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.** Prolonged use of ZOHYDRO ER 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 ZOHYDRO ER. It 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 that could lead to death.

When taking ZOHYDRO ER:

- Do not change your dose. Take ZOHYDRO ER 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 ZOHYDRO ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject 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.**
- Dispose of expired, unwanted, or unused ZOHYDRO ER by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

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, light-headedness when you are 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 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**

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

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