

DRUG FACTS BOX

ZOHYDRO ER (hydrocodone bitartrate)

ZOHYDRO ER tablets are approved for severe, chronic pain that requires around-the-clock opioid treatment

What is the purpose of this box?

To explain the benefits and side effects of ZOHYDRO ER to help you decide whether to use this drug.

Who might consider taking it?

Adults with moderate-to-severe, chronic pain requiring daily, around-the-clock use of opioids for whom alternative treatments are inadequate or not tolerated.

Who should not take it?

People with severe asthma or advanced chronic lung problems such as Chronic Obstructive Pulmonary Disease or COPD; those with a partial or complete blockage of the bowels (paralytic ileus). Use very cautiously in frail, weak elderly patients or in people with a head injury and increased brain pressure. ZOHYDRO ER can be addictive and should be used with caution in people with a history of drug or alcohol abuse or mental-health problems.

What other choices are there?

Non-drug choices: Exercise, weight loss (for back and joint pain), physical therapy, mental-health therapies (such as biofeedback, relaxation, and cognitive behavioral therapy), acupuncture, massage, yoga, and heat therapy.

Other drug choices: Other FDA-approved medications for pain,—acetaminophen; antidepressants; nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen; and other opioids.

BOTTOM LINE

■ Benefits of ZOHYDRO ER

Patients taking ZOHYDRO ER had slightly less pain and were more likely to be satisfied with their treatment than those taking a placebo or sugar pill.

On a scale of 0 to 10, pain worsened by about 1 point for people who took a sugar pill (placebo) compared to 0.5 points for people who took ZOHYDRO ER. About one-third of people who took a sugar pill reported at least “moderate” pain relief compared to about two-thirds of people who took ZOHYDRO ER. Thirty-five percent of people taking a sugar pill said they were very much or completely satisfied with treatment compared to 54 percent of people who took ZOHYDRO ER, but there was no difference in the number of days on which people in either group took “rescue” pain medications.

Patients taking ZOHYDRO ER rated their disability level 3.2 points worse on a 100-point scale, compared to 7.6 points worse for those receiving a placebo. But, people still rated their disability level as severe (53 points) at the end of the study.

■ Risks of ZOHYDRO ER

BLACK BOX WARNING

ZOHYDRO ER carries the most serious FDA warning because it can cause: addiction, fatal overdoses—especially if combined with alcohol—and infant opioid withdrawal symptom if taken during pregnancy.

Note: One patient died from an overdose of ZOHYDRO ER and other opioids during the approval study, highlighting the potential for fatal overdose even under the supervised condition of a trial.

■ Side effects

ZOHYDRO ER caused constipation, nausea, vomiting, abdominal pain, and other side effects typical with opioid medications.

■ How strong is the evidence?

The FDA’s Advisory Committee recommended against approval. A panel of experts from outside the FDA reviewed the evidence and voted 11 to 2 against approving ZOHYDRO ER primarily due to concerns about potential abuse and misuse of the drug as well as diversion into illegal trade. The vote on whether ZOHYDRO ER was effective for long-term use was closely split. Panel members noted that the drug had only a modest effect on pain and were concerned that a 3-month trial was too short to reveal the effects of long-term use.

A short track record means that new, unexpected side effects are possible. ZOHYDRO ER is the first extended-release version of the opioid hydrocodone. Rare, but serious side effects may emerge when people take a new form of a drug. The FDA has required the manufacturer to conduct follow-up studies on the ZOHYDRO ER’s potential for abuse and misuse as well as the the drug’s association with addiction, overdose, and death.

ZOHYDRO ER Study Findings

There was one trial the FDA used to approve ZOHYDRO ER. People who had a pain score of 4 or higher (out of 10) were given ZOHYDRO ER for 6 weeks. Participants were randomly assigned to either keep taking the drug or were given a sugar pill (placebo) for 3 months, and they did not know which they were taking. Here's what happened:

	ZOHYDRO ER (20-100 mg twice a day)	vs.	Placebo (No drug)
How did ZOHYDRO ER help?*			
Daily pain level: Patient's rating of pain on an 11-point scale			
Average change	0.5 points worse	vs.	1 point worse
Percent of people with various changes in pain level			
Worse, little or no change (pain rating changed by less than 1 point)	32%		69%
Moderate relief (pain improved 1 to 1.5 points)	20%		8%
Substantial relief (pain improved 1.5 to 2 points)	41%		19%
Almost complete relief (pain improved 2 points or more)	6%		4%
Disability: patients' rating of disability on a 100-point scale			
Average change	3.2 points worse	vs	7.6 points worse
Patient satisfaction			
Percentage of people "very much" or "completely" satisfied	54%	vs	35%
Need for pain rescue medication			
Days pain rescue medication taken	Both patients in the ZOHYDRO ER and placebo group took additional medication to treat breakthrough pain about 69% of days during the trial.		

What were ZOHYDRO ER's side effects?*

BLACK BOX WARNING

ZOHYDRO ER carries the most serious level of FDA warning because it can cause:

- Opioid addiction, which can lead to overdose and death – even at recommended doses.
- Breathing to stop, especially when starting or increasing the dose. Crushing, chewing or dissolving ZOHYDRO ER can rapidly release the drug and cause a fatal overdose.
- Fatal overdoses in children – even with a single dose.
- Infant opioid withdrawal syndrome – prolonged use during pregnancy can cause the baby to become addicted and experience life-threatening withdrawal at birth.
- Dangerous reaction to alcohol – drinking alcohol with ZOHYDRO ER can cause a fatal overdose.

	ZOHYDRO ER (20-100 mg twice)	vs.	Placebo (No drug)
Symptom side effects			
Constipation (8% more people)	8%	vs.	0%
Nausea (4% more)	7%	vs.	3%
Vomiting (4% more)	5%	vs.	1%
Abdominal pain (3% more)	3%	vs.	0%
Muscle spasms (3% more)	3%	vs.	1%
Leg swelling (3% more)	3%	vs.	0%
Urinary tract infections (2% more)	5%	vs.	2%
Tremor (2% more)	3%	vs.	1%
Sleepiness (1% more)	1%	vs.	0%

Uncommon serious side effects seen with ZOHYDRO ER (or similar drugs)– but level of risk is unknown

- **SIDE EFFECTS TO BE AWARE OF**
 - Can become harder to breathe – especially in people with severe asthma or chronic lung disease.
 - Fainting and lightheadness when standing up (due to low blood pressure).
- **PRECAUTIONS TO TAKE**

Do not take ZOHYDRO ER with the following because it could cause a deadly interaction or overdose:

 - Alcohol
 - Sedatives, anxiolytics, hypnotics, neuroleptics, other opioids, MAO-inhibitors or tricyclic antidepressants

BE CAUTIOUS driving or operating heavy machinery because ZOHYDRO ER causes sleepiness and decreases awareness, making accidents more likely. Let your healthcare provider know if you are pregnant or planning to become pregnant or breastfeeding; ZOHYDRO ER can harm unborn babies and infants.

* Data from FDA Review Documents

This series is produced by Consumer Reports and Consumer Reports Best Buy Drugs, a public information project supported by grants from the state Attorney General Consumer and Prescriber Education Grant Program which is funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin. This brief should not be viewed as a substitute for a consultation with a medical or health professional. It is provided to enhance communication with your doctor, not replace it.

Powered by

