

Medication Guide

HYDROCODONE BITARTRATE (hahy-druh-koh-dohn bahy-tahr-treyt) EXTENDED-RELEASE TABLETS, CII

HYDROCODONE BITARTRATE 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.

Important information about HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS:

- **Get emergency help right away if you take too much HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS (overdose).** When you first start taking HYDROCODONE BITARTRATE 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 HYDROCODONE BITARTRATE 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 HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS. They could die from taking it. Selling or giving away HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS is against the law.
- Store HYDROCODONE BITARTRATE 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 HYDROCODONE BITARTRATE 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 HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- heart rhythm problems (long QT syndrome)
- abuse of street or prescription drugs, alcohol addiction, or mental health problems

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of HYDROCODONE BITARTRATE 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 HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS. It may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS with certain other medicines can cause serious side effects and could lead to death.

When taking HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS:

- Do not change your dose. Take HYDROCODONE BITARTRATE 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 24 hours, at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take your next dose at your usual time the next day.

- Swallow HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS whole. Do not cut, break, chew, crush, dissolve, snort, or inject HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS because this may cause you to overdose and die.
- HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS should be taken 1 tablet at a time. Do not pre-soak, lick, or wet the tablet before placing it 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 HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS without talking to your healthcare provider.**

Dispose of expired, unwanted, or unused HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS, 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 HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS, DO NOT:

- Drive or operate heavy machinery until you know how HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS affects you. HYDROCODONE BITARTRATE 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 HYDROCODONE BITARTRATE EXTENDED-RELEASE TABLETS may cause you to overdose and die.

The possible side effects of HYDROCODONE BITARTRATE 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 HYDROCODONE BITARTRATE 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.**

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

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

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