

Medication Guide

Hydrocodone Bitartrate (hye" droe koe' done bye tar' trate) and Acetaminophen (a seet" a min' oh fen) Oral Solution, CII

Hydrocodone Bitartrate and Acetaminophen Oral Solution is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require an opioid pain medicine and for which alternative treatments are inadequate and when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An 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.

Important information about Hydrocodone Bitartrate and Acetaminophen Oral Solution:

- **Get emergency help or call 911 right away if you take too much Hydrocodone Bitartrate and Acetaminophen Oral Solution (overdose).** When you first start taking Hydrocodone Bitartrate and Acetaminophen Oral Solution, 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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 and Acetaminophen Oral Solution. They could die from taking it. Selling or giving away Hydrocodone Bitartrate and Acetaminophen Oral Solution is against the law.
- Store Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 and Acetaminophen Oral Solution if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- known hypersensitivity to hydrocodone or acetaminophen, or any ingredient in Hydrocodone Bitartrate and Acetaminophen Oral Solution.

Before taking Hydrocodone Bitartrate and Acetaminophen Oral Solution, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems.
- **Tell your healthcare provider if you are:**
- **pregnant or planning to become pregnant.** Prolonged use of Hydrocodone Bitartrate and Acetaminophen Oral Solution during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Hydrocodone Bitartrate and Acetaminophen Oral Solution passes into breast milk and may harm your baby.
- living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking Hydrocodone Bitartrate and Acetaminophen Oral Solution with certain other medicines can cause serious side effects that could lead to death.

When taking Hydrocodone Bitartrate and Acetaminophen Oral Solution:

- Do not change your dose. Take Hydrocodone Bitartrate and Acetaminophen Oral Solution exactly as prescribed by your healthcare provider.
- Always use a calibrated measuring device for Hydrocodone Bitartrate and Acetaminophen Oral Solution to correctly measure your dose. A household teaspoon or tablespoon is not an adequate measuring device. Given the inexactitude of the household spoon measure and the possibility of using a tablespoon instead of a teaspoon, which could lead to overdosage, it is strongly recommended that caregivers obtain and use a calibrated measuring device.

BODY WEIGHT	APPROXIMATE AGE	DOSE EVERY 4 TO 6 HOURS	MAXIMUM TOTAL DAILY DOSE (6 DOSES PER DAY)
12 to 15 kg 27 to 34 lbs.	2 to 3 years	$\frac{3}{4}$ teaspoonful = 3.75 mL	4 $\frac{1}{2}$ teaspoonfuls = 22.5 mL
16 to 22 kg 35 to 50 lbs.	4 to 6 years	1 teaspoonful = 5 mL	6 teaspoonfuls = 30 mL
23 to 31 kg 51 to 69 lbs.	7 to 9 years	1 $\frac{1}{2}$ teaspoonfuls = 7.5 mL	9 teaspoonfuls = 45 mL
32 to 45 kg 70 to 100 lbs.	10 to 13 years	2 teaspoonfuls = 10 mL	12 teaspoonfuls = 60 mL
46 kg and up 101 lbs. and up	14 years to adult	1 Tablespoonful = 15 mL	6 Tablespoonfuls = 90 mL

- Take your prescribed dose. The usual adult dosage is one tablespoonful (15 mL) every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablespoonfuls. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain
- If you have been taking Hydrocodone Bitartrate and Acetaminophen Oral Solution regularly, do not stop taking Hydrocodone Bitartrate and Acetaminophen Oral Solution without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 and Acetaminophen Oral Solution DO NOT:

- Drive or operate heavy machinery, until you know how Hydrocodone Bitartrate and Acetaminophen Oral Solution affects you. Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 and Acetaminophen Oral Solution may cause you to overdose and die.

The possible side effects of Hydrocodone Bitartrate and Acetaminophen Oral Solution:

- 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 or call 911 right away 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 and Acetaminophen Oral Solution. 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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