

DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akom's Customer Service department at 800.932.5676.

MEDICATION GUIDE

Acetaminophen and Codeine Phosphate (a seet' a min' oh fen and koe' deen fos'fate) Oral Solution, 50383-079

Acetaminophen and Codeine Phosphate Oral Solution is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage mild to moderate pain 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 Acetaminophen and Codeine Phosphate Oral Solution:

- **Get emergency help right away if you take too much Acetaminophen and Codeine Phosphate Oral Solution (overdose).** When you first start taking Acetaminophen and Codeine Phosphate 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.
- Taking Acetaminophen and Codeine Phosphate 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 Acetaminophen and Codeine Phosphate Oral Solution. They could die from taking it. Store Acetaminophen and Codeine Phosphate Oral Solution away from children and in a safe place to prevent stealing or abuse. Selling or giving away Acetaminophen and Codeine Phosphate Oral Solution is against the law.

Important Information Guiding Use in Pediatric Patients:

- Do not give Acetaminophen and Codeine Phosphate Oral Solution to a child younger than 12.
- Do not give Acetaminophen and Codeine Phosphate Oral Solution to a child younger than 18 to treat pain after surgery to remove the tonsils and/or adenoids.
- Avoid giving Acetaminophen and Codeine Phosphate Oral Solution to children between 12 to 18 years of age who have risk factors for breathing problems such as obstructive sleep apnea, obesity, or underlying lung problems.

Do not take Acetaminophen and Codeine Phosphate Oral Solution if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- previously had an allergic reaction to codeine or acetaminophen.

Before taking Acetaminophen and Codeine Phosphate 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, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of Acetaminophen and Codeine Phosphate Oral Solution during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Not recommended; may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking Acetaminophen and Codeine Phosphate Oral Solution with certain other medicines can cause serious side effects that could lead to death.

When taking Acetaminophen and Codeine Phosphate Oral Solution:

- Do not change your dose. Take Acetaminophen and Codeine Phosphate Oral Solution exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Always use a calibrated measuring device for Acetaminophen and Codeine Phosphate 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.
- Take your prescribed dose at the same time every day. 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 Acetaminophen and Codeine Phosphate Oral Solution regularly, do not stop taking Acetaminophen and Codeine Phosphate Oral Solution without talking to your healthcare provider.
- After you stop taking Acetaminophen and Codeine Phosphate Oral Solution to properly dispose of the Acetaminophen and Codeine Phosphate Oral Solution flush it down the toilet or dispose of in accordance with local state guidelines and/or regulations.

While taking Acetaminophen and Codeine Phosphate Oral Solution DO NOT:

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

The possible side effects of Acetaminophen and Codeine Phosphate 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 if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, or hands, hives, itching, rash, extreme drowsiness, lightheadedness 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 Acetaminophen and Codeine Phosphate Oral Solution. Call your doctor for medical advice about side effects. You may report side effects to Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088.

For more information go to dailymed.nlm.nih.gov.

Manufactured by:
Hi-Tech Pharmacal Co., Inc.
Amityville, NY 11701

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

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