

## **Medication Guide**

### **Acetaminophen and Codeine Phosphate Tablets USP, CIII (a seet' a min' oh fen and koe' deen fos' fate)**

#### **Acetaminophen and codeine phosphate tablets are:**

- 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 tablets:**

- **Get emergency help right away if you take too many acetaminophen and codeine phosphate tablets (overdose).** When you first start taking acetaminophen and codeine phosphate 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 acetaminophen and codeine 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 acetaminophen and codeine phosphate tablets. They could die from taking it. Store acetaminophen and codeine phosphate tablets away from children and in a safe place to prevent stealing or abuse. Selling or giving away acetaminophen and codeine phosphate tablets is against the law.

#### **Important Information Guiding Use in Pediatric Patients:**

- Do not give acetaminophen and codeine phosphate tablets to a child younger than 12 years of age.
- Do not give acetaminophen and codeine phosphate tablets to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving acetaminophen and codeine phosphate tablets 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 tablets if you have:**

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

#### **Before taking acetaminophen and codeine phosphate tablets, 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
- Have been told by your healthcare provider that you are a “rapid metabolizer” of certain medicines.

#### **Tell your healthcare provider if you are:**

- **pregnant or planning to become pregnant.** Prolonged use of acetaminophen and codeine phosphate tablets 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 tablets with certain other medicines can cause serious side effects that could lead to death.

#### **When taking acetaminophen and codeine phosphate tablets:**

- Do not change your dose. Take acetaminophen and codeine phosphate tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.

- Take your prescribed dose every 4 hours as needed. Do not take more than your prescribed dose. If you miss a dose, take your next dose when needed.
- Call your healthcare provider if the dose you are taking does not control your pain.
  - If you have been taking acetaminophen and codeine phosphate tablets regularly, do not stop taking acetaminophen and codeine phosphate tablets without talking to your healthcare provider.
  - After you stop taking acetaminophen and codeine phosphate tablets, dispose of any unused tablets in accordance with local state guidelines and/or regulations.

**While taking acetaminophen and codeine phosphate tablets DO NOT:**

- Drive or operate heavy machinery, until you know how acetaminophen and codeine phosphate tablets affect you. Acetaminophen and codeine phosphate 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 acetaminophen and codeine phosphate tablets may cause you to overdose and die.

**The possible side effects of acetaminophen and codeine phosphate tablets:**

- 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 acetaminophen and codeine phosphate 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](http://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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