

Medication Guide

Codeine Sulfate (koe' deen sul' fate) Tablets, USP CII

Codeine Sulfate Tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage mild to moderate pain, where treatment with an opioid is appropriate, 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 Codeine Sulfate Tablets:

- **Get emergency help or call 911 right away if you take too much codeine sulfate tablets (overdose).** When you first start taking codeine sulfate 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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking codeine sulfate 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 codeine sulfate tablets. They could die from taking it. Selling or giving away codeine sulfate tablets is against the law.
- Store codeine sulfate tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Important Information Guiding Use in Pediatric Patients:

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

- Severe asthma, trouble breathing, or other lung problems.
- A bowel blockage or have narrowing of the stomach or intestines.
- An allergy to codeine sulfate tablets or any of the ingredients.

Before taking Codeine Sulfate 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, opioid overdose, 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:

- **noticing your pain getting worse.** If your pain gets worse after you take codeine sulfate tablets, do not take more of codeine sulfate tablets without first talking to your healthcare provider. Talk to your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking codeine sulfate tablets.
- **pregnant or planning to become pregnant.** Use of codeine sulfate tablets for an extended period of time 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.
- 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 codeine sulfate with certain other medicines can cause serious side effects that could lead to death.

When taking Codeine Sulfate Tablets:

- Do not change your dose. Take codeine sulfate tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- For acute (short-term) pain, you may only need to take codeine sulfate tablets for a few days. You may have some codeine sulfate tablets left over that you did not use. See disposal information at the bottom of this section for directions on how to safely throw away (dispose of) your unused codeine sulfate tablets.
- Take your prescribed dose every 4 hours as needed for pain. 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 codeine sulfate tablets regularly, do not stop taking codeine sulfate without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused codeine sulfate tablets by taking your drug to an authorized DEA-registered collector or drug take-back program. If one is not available, you can dispose of codeine sulfate tablets by mixing the product with dirt, cat litter, or coffee grounds; placing the mixture in a sealed plastic bag and throwing the bag in your trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking Codeine Sulfate Tablets DO NOT:

- Drive or operate heavy machinery, until you know how codeine sulfate affects you. Codeine sulfate 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 codeine sulfate may cause you to overdose and die.

The possible side effects of Codeine Sulfate 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 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.
- If you are a nursing mother taking codeine sulfate tablets and your breastfeeding baby has increased sleepiness, confusion, difficulty breathing, shallow breathing, limpness, or difficulty breastfeeding.

These are not all the possible side effects of codeine sulfate. Call your healthcare provider 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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For more information, please call 1-844-834-0530.

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