

Medication Guide

Codeine Sulfate (koe' deen sul' fate) Oral Solution USP CII

Rx only

Codeine Sulfate Oral Solution is:

- 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 Oral Solution:

- **Get emergency help right away if you take too much Codeine Sulfate Oral Solution (overdose).** When you first start taking Codeine Sulfate 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 Codeine Sulfate 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 Codeine Sulfate Oral Solution. They could die from taking it. Selling or giving away Codeine Sulfate Oral Solution is against the law.
- Store Codeine Sulfate Oral Solution 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 Oral Solution to a child younger than 12 years of age.
- Do not give Codeine Sulfate Oral Solution to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving Codeine Sulfate 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 Codeine Sulfate Oral Solution 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 Oral Solution or any of the ingredients.
- Do not give Codeine Sulfate Oral Solution to a child to treat pain after tonsillectomy and/or adenoidectomy surgery.

Before taking Codeine Sulfate Oral Solution, tell your healthcare provider if you have a history of:

- Head injury, seizures
- Problems urinating
- Abuse of street or prescription drugs, alcohol addiction, or mental health problems
- Liver, kidney, thyroid problems
- Pancreas or gallbladder 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 codeine sulfate 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 codeine sulfate with certain other medicines can cause serious side effects that could lead to death.

When taking Codeine Sulfate Oral Solution:

- Do not change your dose. Take Codeine Sulfate Oral Solution exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- See the detailed Instructions for Use for information about how to take Codeine Sulfate Oral Solution.
- Always use the calibrated oral syringe or measuring cup that comes with Codeine Sulfate Oral Solution to correctly measure your dose. Never use a household teaspoon or tablespoon to measure Codeine Sulfate Oral Solution.
- 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 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 Oral Solution regularly, do not stop taking Codeine Sulfate Oral Solution without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused Codeine Sulfate Oral Solution 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 Oral Solution 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.

While taking Codeine Sulfate Oral Solution 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 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, 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 Oral Solution 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 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

Distr. by: **West-Ward
Pharmaceuticals Corp.**

Eatontown, NJ 07724

For more information, please call West-Ward Pharmaceuticals Corp. at 1-800-962-8364.

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

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Instructions for Use**Codeine Sulfate (koe' deen sul' fate) Oral Solution USP CII****Oral Syringe****Important information about measuring Codeine Sulfate Oral Solution:**

- Always use the oral syringe provided with your Codeine Sulfate Oral Solution to make sure you measure the right amount.
 - Measure the dose of medicine from the widest part of the plunger. Do not measure from the narrow tip. See Figure 1.
1. Remove the protective storage cap from the syringe.
 2. Insert the tip of the oral syringe into the medicine bottle.
 3. Pull back the plunger to the line that matches the dose prescribed by your healthcare provider.
 4. Remove the oral syringe from the medicine bottle.
 5. Take your medicine by slowly pushing the plunger until the oral syringe is empty.
 6. Replace the cap and oral syringe in a dry and clean place.

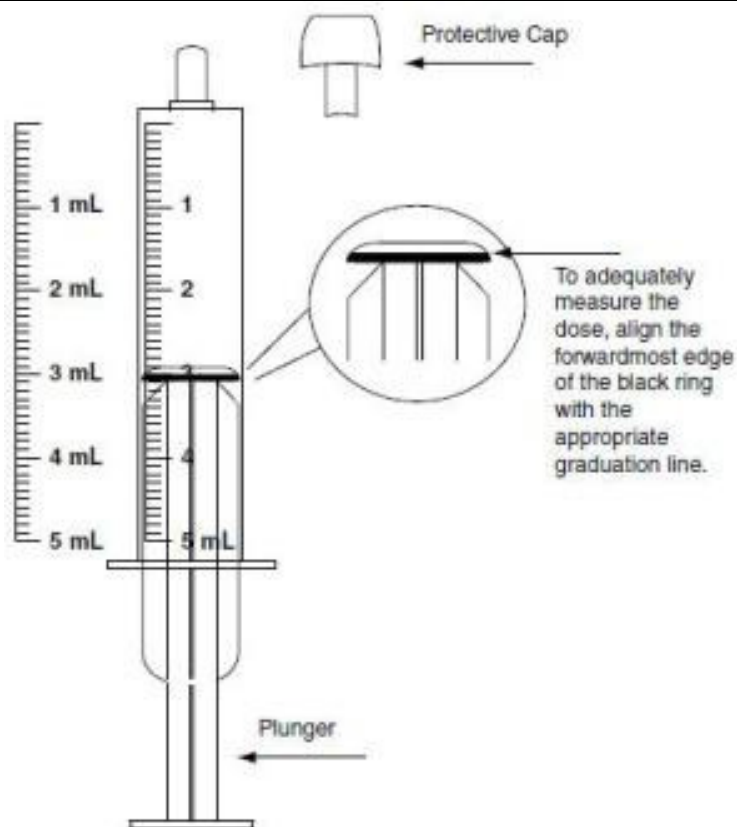


Figure 1

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

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