- Advise patients that safe use in pregnancy has not been established and prolonged use of opioid analgesics during pregnancy may cause fetal-neonatal physical dependence, and neonatal withdrawal may occur.

Manufactured by:
Roxane Laboratories, Inc., Columbus, Ohio 43216

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MEDICATION GUIDE

CODEINE SULFATE (koh-deen) CII
Oral Solution

IMPORTANT:

- **Do not give CODEINE Sulfate Oral Solution to a child to treat pain after tonsillectomy or adenoidectomy surgery.**
  - **When you take CODEINE Sulfate Oral Solution, some or all of it changes into morphine in your body.**
  - **In some children and adults this happens very quickly, and can cause you to stop breathing and cause death due to an overdose.**
- **Women who breastfeed should talk to their healthcare provider before taking CODEINE Sulfate Oral Solution.**
  - **When you take CODEINE Sulfate Oral Solution, some or all of it changes into morphine in your body.**
  - **In some women, this happens very quickly. Codeine and morphine pass into your breast milk. A large amount of morphine can cause your baby to die.**
- **Call your healthcare provider or get emergency medical help right away if anyone taking CODEINE Sulfate Oral Solution, or your breastfeeding baby has any of the symptoms listed below:**
  - **Increased sleepiness**
  - **Confusion**
  - **Difficulty breathing**
  - **Shallow breathing**
  - **Limpness**
  - **Your baby has difficulty breastfeeding**
- **Keep Codeine Sulfate Oral Solution in a safe place away from children. Accidental use by a child is a medical emergency and can cause death. If a child accidentally takes Codeine Sulfate, get emergency help right away.**

Read the Medication Guide that comes with Codeine Sulfate Oral Solution before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Codeine Sulfate Oral Solution?

- Codeine Sulfate Oral Solution can cause serious side effects, including death.
- Take Codeine Sulfate Oral Solution exactly as prescribed by your healthcare provider. If you take the wrong dose or strength of Codeine Sulfate Oral Solution, you could overdose and die.

- It is especially important when you take Codeine Sulfate Oral Solution that you know exactly what dose and strength to take, and the right way to measure your medicine. Your healthcare provider or pharmacist should show you the right way to measure your medicine.
- Always use the oral syringe provided with Codeine Sulfate Oral Solution, 30 mg per 5 mL (6 mg/mL) to help make sure you measure the right amount.

What is Codeine Sulfate Oral Solution?

- Codeine Sulfate Oral Solution is in a group of drugs called narcotic pain relievers. Codeine Sulfate Oral Solution is only for people who have mild to moderately severe pain.
- Codeine Sulfate Oral Solution is a federally controlled substance (CII) because it is an opioid pain medicine that can be abused by people who abuse prescription medicines or street drugs.
- Prevent theft, misuse or abuse. Keep Codeine Sulfate Oral Solution in a safe place to keep it from being stolen. Codeine Sulfate can be a target for people who misuse or abuse prescription medicines or street drugs.
- Never give Codeine Sulfate Oral Solution to anyone else, even if they have the same symptoms you have. It may harm them or even cause death.
- Selling or giving away this medicine is against the law.
- It is not known if Codeine Sulfate Oral Solution is safe and effective in children under age 18 years of age.

Who should not take Codeine Sulfate Oral Solution?

- Do not give Codeine Sulfate Oral Solution to a child to treat pain after tonsillectomy or adenoidectomy surgery.
- Do not take Codeine Sulfate Oral Solution if you:
  - are allergic to Codeine or any of the ingredients in Codeine Sulfate Oral Solution. See the end of this Medication guide for a complete list of ingredients in Codeine Sulfate Oral Solution.
  - are having an asthma attack or have severe asthma, trouble breathing, or lung problems.
  - have a bowel blockage, called paralytic ileus.

What should I tell my healthcare provider before taking Codeine Sulfate?

- Before taking Codeine Sulfate Oral Solution, tell your healthcare provider if you:
  - have trouble breathing or lung problems
  - have had a head injury
  - have liver or kidney problems
  - have been told by your healthcare provider that you are a "rapid metabolizer" of certain medicines
  - have had adrenal gland problems, such as Addison's disease
  - have severe scoliosis that affects your breathing
  - have thyroid problems
  - have problems urinating or enlargement of your prostate
  - have had convulsions or seizures
  - have a past or present drinking problem or alcoholism
  - have severe mental problems
  - have constipation or other bowel problems
  - have problems with your pancreas or gallbladder
  - have past or present substance abuse or drug addiction
  - plan to have surgery
  - have any other medical conditions

- are pregnant or plan to become pregnant. It is not known if Codeine Sulfate Oral Solution will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant. If you take Codeine Sulfate Oral Solution right before your baby is born, your newborn could have breathing problems. Your baby may also have withdrawal symptoms because his body has become used to the medicine. Symptoms of withdrawal in a newborn baby may include:
  - irritability
  - vomiting
  - weight loss
  - fever
  - diarrhea or more stools than normal
  - being very active
  - problems sleeping
  - high pitched cry
  - shaking (tremors)
- are breast-feeding or plan to breast-feed
  - See the box with Important information at the top of this Medication Guide.
  - If you stop breast-feeding, your baby may have withdrawal symptoms. See the list of withdrawal symptoms above. If your baby has any of these symptoms you need to contact your healthcare provider right away. If you can not reach your healthcare provider, take your baby to your local hospital emergency room or call your local emergency medical service. You and your healthcare provider should decide if you will take Codeine Sulfate Oral Solution or breast-feed.

- Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Sometimes the doses of medicines that you take with Codeine Sulfate Oral Solution may need to be changed if used together. Codeine Sulfate Oral Solution and other medicines may affect each other causing serious side effects. Be especially careful about taking other medicines that make you sleepy such as:
  - sleeping pills
  - anti-depressants
  - other pain medicines
  - anticholinergic medicines
  - anti-nausea medicines
  - antibiotic or antifungal medicines
  - tranquilizers
  - heart medicines
  - antihistamines
  - anti-seizure medicines
  - anti-anxiety medicines
- Do not take Codeine Sulfate Oral Solution if you already take a monoamine oxidase inhibitor medicine (MAOI) or within 14 days after you stop taking an MAOI medicine.
- Do not take any new medicine while using Codeine Sulfate until you have talked with your healthcare provider or pharmacist. They will tell you if it is safe to take other medicines with Codeine Sulfate Oral Solution.
- Ask your healthcare provider if you are not sure if your medicine is one listed above.
- Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take Codeine Sulfate Oral Solution?

- See "What is the most important information I should know about Codeine Sulfate Oral Solution?"

- **Take Codeine Sulfate Oral Solution exactly as prescribed.** Do not change your dose unless your healthcare provider tells you to. Your healthcare provider may change your dose after seeing how the medicine affects you. Call your healthcare provider if your pain is not well controlled with your prescribed dose of Codeine Sulfate Oral Solution. **You can take Codeine Sulfate Oral Solution with or without food.**
- **Make sure you understand exactly how to measure your dose.** Always use the oral syringe provided with your Codeine Sulfate Oral Solution, 30 mg per 5 mL (6 mg/mL) to help make sure you measure the right amount. Ask your healthcare provider or pharmacist if you are not sure what dose of Codeine Sulfate Oral Solution you should take or if you are not sure how to use the oral syringe.
- **Do not stop taking Codeine Sulfate Oral Solution suddenly.** If you have been taking Codeine Sulfate Oral Solution for more than a few weeks, stopping Codeine Sulfate Oral Solution suddenly can make you sick with withdrawal symptoms (for example, nausea, vomiting, diarrhea, anxiety, and shivering). If your healthcare provider decides you no longer need Codeine Sulfate Oral Solution, ask how to slowly reduce this medicine. Do not stop taking Codeine Sulfate Oral Solution without talking to your healthcare provider.

  If you take too much Codeine Sulfate Oral Solution, call your healthcare provider or go to the nearest hospital emergency room right away.
- **If you miss one dose of Codeine Sulfate Oral Solution** you can take the dose when you remember it if you have pain, or you can wait for the next dose.
- Talk with your healthcare provider regularly about your pain to see if you still need to take Codeine Sulfate.

What should I avoid while taking Codeine Sulfate Oral Solution?

- You should not drink alcohol while using Codeine Sulfate Oral Solution. Drinking alcohol with Codeine Sulfate Oral Solution may increase your risk of having dangerous side effects or death.
- **Do not drive, operate heavy machinery, or do other dangerous activities,** especially when you start taking Codeine Sulfate Oral Solution and when your dose is changed, until you know how Codeine Sulfate Oral Solution affects you. Codeine Sulfate Oral Solution can make you sleepy. Ask your healthcare provider to tell you when it is okay to do these activities.

What are the possible side effects of Codeine Sulfate Oral Solution?

- **See "What is the most important information I should know about Codeine Sulfate Oral Solution?"**

- Codeine Sulfate Oral Solution can cause serious breathing problems that can become life-threatening, especially if Codeine Sulfate is used the wrong way. Call your healthcare provider or get help right away if:

  - your breathing slows down
  - you have shallow breathing (little chest movement with breathing)
  - you feel faint, dizzy, confused, or
  - you have any other unusual symptoms

These can be symptoms that you have taken too much Codeine Sulfate Oral Solution (overdose) or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away.**

- **Codeine Sulfate Oral Solution can cause your blood pressure to drop.** This can make you feel dizzy if you get up fast from sitting or lying down. Low blood pressure is also more likely to happen if you take other medicines that can also lower your blood pressure. Severe low blood pressure can happen if you lose blood or take certain other medicines.
- **There is a risk of abuse or addiction with Codeine Sulfate Oral Solution.** The risk is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.

- **Codeine Sulfate Oral Solution can cause physical dependence.** Do not stop taking Codeine Sulfate Oral Solution or any other opioid without talking to your healthcare provider about how to slowly stop your medicine. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependence is not the same as drug addiction. Tell your healthcare provider if you have any of these symptoms of withdrawal while slowly stopping Codeine Sulfate Oral Solution:
  - feel restless
  - dilated pupils of your eyes
  - tearing eyes
  - feel irritable or anxious
  - runny nose
  - trouble sleeping
  - yawning
  - increase in your blood pressure
  - sweating
  - faster breathing, or faster heart beats
  - chills or hair on your arms "stand up"
  - nausea, loss of appetite, vomiting, diarrhea, stomach-area (abdominal) cramps
  - muscle aches, backache
- Common side effects of Codeine Sulfate Oral Solution include:
  - constipation
  - dizziness
  - nausea
  - drowsiness
  - sleepiness
  - vomiting
  - lightheadedness
  - sweating

- Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines from the opioid class. Talk to your healthcare provider about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking Codeine Sulfate Oral Solution.
- Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
- These are not all the possible side effects of Codeine Sulfate Oral Solution. For more information, ask your healthcare provider or pharmacist.
- Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Codeine Sulfate Oral Solution?

- Store Codeine Sulfate Oral Solution at room temperature, between 59°F to 86°F (15°C to 30°C), away from the light.
- Keep Codeine Sulfate Oral Solution out of the reach of children. Accidental overdose by a child is a medical emergency and can lead to death.

General Information about Codeine Sulfate Oral Solution

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Codeine Sulfate Oral Solution for a condition for which it was not prescribed. Do not give your Codeine Sulfate Oral Solution to other people, even if they have the same symptoms you have. Selling or giving away Codeine Sulfate Oral Solution may harm others, may cause death, and is against the law.
- This Medication Guide summarizes the most important information about Codeine Sulfate Oral Solution. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Codeine Sulfate Oral Solution that is written for healthcare professionals.

- For more information about Codeine Sulfate Oral Solution, go to www.roxane.com or call Roxane Laboratories, Inc. at 1-800-962-8364.

What are the ingredients in Codeine Sulfate Oral Solution?

- Active ingredient: codeine sulfate

Inactive ingredients: ascorbic acid, citric acid, disodium edetate, FD&C Red No.40, FD&C Yellow No.6, glycerin, Orange Flavor XBF-709818 (artificial flavors, propylene glycol), sodium benzoate, sorbitol, sucralose and water.

Instructions for Use
Codeine Sulfate (koh-deen) (CII)
Oral Solution

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.

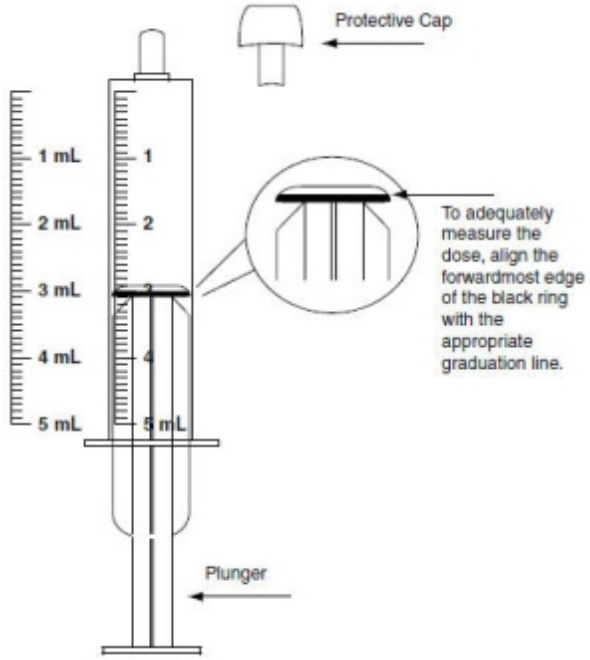

Figure 1

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

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