Codeine Sulfate Tablets (codeine sulfate) - Drug Summary

Roxane Laboratories, Inc.

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Codeine Sulfate (codeine sulfate)

BOXED WARNING

Respiratory depression and death reported in children who received codeine following tonsillectomy and/or adenoidectomy and had evidence of being ultra-rapid metabolizers of codeine due to a CYP2D6 polymorphism.

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Mild to Moderately Severe Pain

Usual: 15-60mg (2.5-10mL) repeated up to q4h prn
Max: 360mg/24 hrs

DOSING CONSIDERATIONS

Renal Impairment
Start at lower dose or w/ longer dosing intervals and titrate slowly

Hepatic Impairment
Start at lower dose or w/ longer dosing intervals and titrate slowly

Discontinuation
Taper dose gradually

Elderly
Start at lower end of dosing range

ADMINISTRATION

Oral route

HOW SUPPLIED

Sol: 30mg/5mL [500mL]; Tab: 15mg*, 30mg*, 60mg* *scored

CONTRAINDICATIONS

Postoperative pain management in children who have undergone tonsillectomy and/or adenoidectomy, hypersensitivity to codeine or any components of the product, respiratory depression in the absence of resuscitative equipment, acute or severe bronchial asthma or hypercarbia, known or suspected paralytic ileus.

WARNINGS/PRECAUTIONS

Ultra-rapid metabolizers, due to specific CYP2D6 genotype (gene duplications denoted as *1/*1xN or *1/*2xN), may have life-threatening or fatal respiratory depression or experience signs of overdose. Produces dose-related respiratory depression; increased risk in elderly/debilitated patients and in those w/ conditions accompanied by

hypoxia, hypercapnia, or upper airway obstruction. Caution when used postoperatively, in patients w/ pulmonary disease or SOB, or w/ depressed ventilatory function. Extreme caution w/ COPD or cor pulmonale, and in patients having a substantially decreased respiratory reserve (eg, severe kyphoscoliosis), hypoxia, hypercapnia, or preexisting respiratory depression; consider alternative nonopioid analgesics. High potential for abuse. May markedly exaggerate respiratory depressant effects and capacity to elevate CSF pressure in the presence of head injury, intracranial lesions, or preexisting increase in intracranial pressure; may obscure clinical course of patients w/ head injuries. May cause severe hypotension when ability to maintain BP has been compromised by a depleted blood volume. May produce orthostatic hypotension and syncope in ambulatory patients. Avoid w/ GI obstruction, especially paralytic ileus; may obscure diagnosis or clinical course w/ acute abdominal conditions. Chronic use may result in obstructive bowel disease, especially w/ intestinal motility disorder. May cause/aggravate constipation. Caution w/ biliary tract disease (eg, acute pancreatitis); may cause spasm of the sphincter of Oddi and diminish biliary and pancreatic secretions. Caution in patients w/ circulatory shock, severe renal/hepatic impairment, hypothyroidism, Addison's disease, prostatic hypertrophy, urethral stricture, CNS depression, acute alcoholism, delirium tremens, and in elderly/debilitated. May aggravate convulsions in patients w/ convulsive disorders and may induce or aggravate seizures. May impair mental/physical abilities. May elevate plasma amylase and lipase. Give the lowest effective dose for the shortest period of time. (Sol) Not recommended for use in women during and immediately prior to labor. (Tab) Avoid during labor if delivery of a premature infant is anticipated.

ADVERSE REACTIONS

Respiratory/circulatory depression, respiratory arrest, shock, cardiac arrest, drowsiness, lightheadedness, dizziness, sedation, SOB, N/V, sweating, constipation.

DRUG INTERACTIONS

May result in additive CNS/respiratory depression, hypotension, profound sedation, or coma when used w/ other opioids, illicit drugs, antihistamines, antipsychotics, antianxiety agents, or other CNS depressants (eg, sedatives, hypnotics, general anesthetics, phenothiazines, alcohol); use w/ caution and in reduced dosages when taking these agents. Avoid w/ mixed agonist/antagonist analgesics (eg, pentazocine, nalbuphine, butorphanol); may reduce analgesic effect and/or may precipitate withdrawal symptoms. May result in increased risk of urinary retention and/or severe constipation, w/ anticholinergics or other medications w/ anticholinergic activity, which may lead to paralytic ileus. Concurrent use w/ MAOIs or TCAs may increase the effect of either the antidepressant or codeine; avoid use w/ MAOIs or w/in 14 days of stopping such treatment. Concomitant use w/ CYP2D6 inhibitors or CYP3A4 inducers/inhibitors may result in an altered response to codeine; monitor analgesic activity. If coadministration is necessary, caution when initiating therapy w/, currently taking, or discontinuing CYP450 inhibitors/inducers; evaluate patients at frequent intervals and consider dose adjustments until stable drug effects are achieved.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Opioid analgesic; not established. Specific CNS opiate receptors and endogenous compounds w/ morphine-like activity have been identified throughout the brain and spinal cord and are likely to play a role in the expression and perception of analgesic effects.

PHARMACOKINETICS

Absorption: T_{max}=60 min. **Distribution:** V_d=3-6L/kg; plasma protein binding (7-25%); crosses placenta, found in breast milk. **Metabolism:** Via UDP-glucuronosyltransferase 2B7 and 2B4, CYP2D6 and 3A4; conjugation, O- and N-demethylation; morphine (active metabolite). **Elimination:** Kidney (90%, 10% unchanged); $T_{1/2}$=3 hrs.

ASSESSMENT

Assess for hypersensitivity to the drug, risk factors for and/or history of abuse or addiction, abuse potential, pain severity, respiratory depression, COPD or other respiratory complications, GI obstruction, paralytic ileus, renal/hepatic impairment, pregnancy/nursing status, possible drug interactions, and any other conditions where treatment is contraindicated or cautioned.

MONITORING

Monitor for respiratory depression, CSF pressure elevation, hypotension, syncope, occurrence/aggravation of constipation/convulsions/seizures, tolerance, physical dependence, and other adverse reactions. Closely monitor newborn infants for signs of respiratory depression if the mother received the drug during labor.

PATIENT COUNSELING

Advise to take only ud and not to adjust dose w/o consulting a physician. Caution against performing hazardous tasks (eg, operating machinery/driving). Advise not to combine w/ alcohol or CNS depressants during therapy except by the orders of the physician. Inform that drug has potential for abuse. Inform of potential for severe constipation. Advise patients who have genetic variation that overdose symptoms may occur. Instruct to inform physician prior to therapy if pregnant/planning to become pregnant. Counsel on the importance of safely tapering the dose. Advise of the most common adverse events that may occur (eg, drowsiness, lightheadedness, dizziness, sedation, SOB, N/V, constipation, sweating). (Sol) Instruct on how to measure and take the correct dose.

STORAGE

Protect from moisture and light. 20-25°C (68-77°F). (Sol) excursions permitted between 15-30°C (59-86°F).

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