Carisoprodol, Aspirin and Codeine Phosphate (aspirin/carisoprodol/codeine phosphate) - Drug Summary

Eon labs, Inc.

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Carisoprodol, Aspirin and Codeine (aspirin/carisoprodol/codeine phosphate)

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 CYP2D6 polymorphism.

THERAPEUTIC CLASS

Analgesic/central muscle relaxant

DEA CLASS

CIII

ADULT DOSAGE & INDICATIONS

Musculoskeletal Conditions

Relief of discomfort associated w/ acute, painful musculoskeletal conditions

16-65 Years:
Usual: 1 or 2 tabs qid
Max Daily Dose: 2 tabs qid
Max Duration of Use: Up to 2 or 3 weeks

ADMINISTRATION

Oral route

HOW SUPPLIED

Tab: (Aspirin [ASA]/Carisoprodol/Codeine Phosphate) 325mg/200mg/16mg

CONTRAINDICATIONS

History of a serious GI complication (eg, bleeding, perforations, obstruction) due to ASA use, ASA-induced asthma (a symptom complex which occurs in patients who have asthma, rhinosinusitis, and nasal polyps who develop a severe, potentially fatal bronchospasm shortly after taking ASA or other NSAIDs), hypersensitivity reaction to a carbamate (eg, meprobamate), or acute intermittent porphyria. Codeine: Postoperative pain management in children who have undergone tonsillectomy and/or adenoidectomy.

WARNINGS/PRECAUTIONS

Carisoprodol/Codeine: Has sedative properties; may impair mental/physical abilities. Has been subject to abuse, dependence, withdrawal, misuse, and criminal diversion. Tolerance reported with prolonged use. Withdrawal symptoms reported following abrupt cessation. ASA/Codeine: Use lowest effective dose for the shortest possible duration. Carisoprodol: Caution with renal/hepatic impairment or reduced CYP2C19 activity. Seizures reported. ASA: May cause serious GI adverse reactions including bleeding, perforation, and obstruction of the stomach, small intestine, or large intestine, which can be fatal; increased risk in patients with a history of ASA-associated ulcers (uncomplicated ulcers) or GI bleeding from ulcers (complicated ulcers), geriatric patients, patients with poor baseline health status, and patients taking higher doses of ASA. May cause an increased risk of serious anaphylaxis and anaphylactoid reactions. Associated with gastritis, GI erosions, abdominal pain, heartburn, and

N/V. Avoid therapy starting at 30 weeks gestation. Codeine: Deaths reported in nursing infants exposed to high levels of morphine because their mothers were ultra-rapid metabolizers of codeine. 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 (eg, extreme sleepiness, confusion, shallow breathing). May cause respiratory depression; increased risk in geriatric/debilitated patients, non-tolerant patients who are given large initial doses of opioids, patients with chronic obstructive pulmonary disease, restrictive lung disease, decreased respiratory drive, and/or respiratory depression. Opioid-associated respiratory depression may be increased in patients with increased intracranial pressure (eg, head trauma, intracranial lesions). May cause GI obstruction and hypotension; increased risk of hypotension with dehydration. May obscure clinical course of medical conditions (eg, head injuries, acute abdominal conditions). May cause spasm of the sphincter of Oddi and diminish pancreatic and/or biliary secretions; caution with pancreatic or biliary duct disease.

ADVERSE REACTIONS

Abdominal pain, anorexia, N/V, gastritis, occult bleeding, tachycardia, postural hypotension, drowsiness, dizziness, vertigo, tremor, syncope, leukopenia, constipation.

DRUG INTERACTIONS

Carisoprodol/Codeine: Additive sedative effects with other CNS depressants (eg, alcohol, benzodiazepines, other opioids, TCAs, other skeletal muscle relaxants); caution when coadministering. Carisoprodol: Not recommended with meprobamate. Increased exposure of carisoprodol and decreased exposure of meprobamate with CYP2C19 inhibitors (eg, omeprazole, fluvoxamine). Decreased exposure of carisoprodol and increased exposure of meprobamate with CYP2C19 inducers (eg, rifampin, St. John's wort). ASA: Increased risk of GI bleeding with ≥3 alcoholic drinks or anticoagulants (eg, heparin, warfarin, clopidogrel). Can displace warfarin from protein binding sites, leading to prolongation of INR. May diminish hypotensive effects of ACE inhibitors, ARBs, β-blockers, and diuretics. May increase serum concentrations of acetazolamide. Corticosteroids and antacids may decrease levels. May enhance methotrexate toxicity. Increased risk of serious GI adverse reactions with NSAIDs. May increase serum glucose-lowering action of insulin and sulfonylureas, leading to hypoglycemia. Ammonium chloride and other drugs that acidify the urine can elevate plasma concentrations. Antagonizes uricosuric action of probenecid and sulfinpyrazone. Induction effect on CYP2C19 seen with low-dose ASA. Codeine: Increased risk of respiratory depression with concomitant respiratory depressants (eg, other opioids, benzodiazepines, TCAs, phenothiazines, skeletal muscle relaxants, alcohol). Increased risk of hypotension with concomitant drugs associated with hypotension.

PREGNANCY AND LACTATION

Category D, not for use in nursing.

MECHANISM OF ACTION

Carisoprodol: Centrally-acting muscle relaxant; not established. (Animals) Muscle relaxation induced is associated with altered interneuronal activity in the spinal cord and in the descending reticular formation of the brain. ASA: Non-narcotic analgesic; inhibits body's production of prostaglandins, which are thought to cause pain sensations by stimulating muscle contractions and dilating blood vessels. Codeine: Centrally acting narcotic-analgesic; not established. Probably due to its conversion to morphine. Binding to mu, delta, and kappa opioid receptors in the CNS may change perception of pain.

PHARMACOKINETICS

Absorption: Carisoprodol: T_{max}=1.7 hrs, 4.5 hrs (meprobamate); AUC=7mcg•hr/mL, 46mcg•hr/mL (meprobamate); C_{max}=1.8mcg/mL, 2.5mcg/mL (meprobamate). ASA: T_{max}=1-2 hrs (salicylic acid). Codeine: Readily absorbed from the GI tract. **Distribution:** ASA/Codeine: Found in breast milk. ASA: (Salicylic Acid) Plasma albumin binding (90%, <100mcg/mL), (76%, >400mcg/mL). **Metabolism:** Carisoprodol: Liver via CYP2C19; meprobamate (primary metabolite). ASA: Plasma (hydrolysis) then liver (conjugation); salicylic acid (metabolite). Codeine: CYP2D6; morphine (active metabolite). **Elimination:** Carisoprodol: Renal and nonrenal routes; $T_{1/2}$=2 hrs, 9.6 hrs (meprobamate). ASA: Urine; $T_{1/2}$=15 min. Codeine: Urine (90%), feces; $T_{1/2}$=2.9 hrs.

ASSESSMENT

Assess for history of a serious GI complication due to ASA use, ASA-induced asthma, hypersensitivity reaction to a carbamate, and acute intermittent porphyria, and for risk of abuse, risk for GI adverse reactions or respiratory depression, any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of sedation, abuse, dependence, withdrawal, overdose, GI events adverse reactions, anaphylaxis, anaphylactoid reactions, respiratory depression, hypotension, and other adverse reactions.

PATIENT COUNSELING

Advise to avoid taking the drug before engaging in potentially hazardous activities (eg, driving, operating machinery). Instruct to avoid alcoholic beverages and to check with physician before taking other CNS depressants. Advise that treatment should be limited to acute use; instruct to contact physician for further evaluation if musculoskeletal symptoms still persist. Warn that drug can cause epigastric discomfort, gastric and duodenal ulcers, and serious GI adverse reactions; instruct to seek medical attention if symptoms of GI bleeding or ulcers occur. Counsel patients who consume ≥3 alcoholic drinks a day about the GI bleeding risks. Instruct to seek immediate emergency help if symptoms of an anaphylactoid reaction or anaphylaxis occur. Advise to take appropriate measures to reduce risk of constipation (eg, dietary changes, laxatives). Educate about abuse and on proper storage and disposal. Instruct patients taking large doses or those taking the drug for a prolonged time to not abruptly d/c therapy.

STORAGE

20-25°C (68-77°F). Protect from moisture.

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PDR
Information for better health