Synalgos-DC (aspirin/caffeine/dihydrocodeine bitartrate) - Drug Summary

Caraco Pharmaceutical Laboratories, Ltd.

Related Drug Information ▼

Synalgos-DC (aspirin/caffeine/dihydrocodeine bitartrate)

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

Opioid analgesic

DEA CLASS

CIII

ADULT DOSAGE & INDICATIONS

Moderate to Moderately Severe Pain

Usual: 2 caps q4h prn

PEDIATRIC DOSAGE & INDICATIONS

Moderate to Moderately Severe Pain

≥12 Years:
Usual: 2 caps q4h prn

DOSING CONSIDERATIONS

Elderly
Use caution; start at low end of dosing range

ADMINISTRATION

Oral route

HOW SUPPLIED

Cap: (Dihydrocodeine/Aspirin [ASA]/Caffeine) 16mg/356.4mg/30mg

CONTRAINDICATIONS

Postoperative pain management in children who have undergone tonsillectomy and/or adenoidectomy.

WARNINGS/PRECAUTIONS

Caution in elderly/debilitated patients. Dihydrocodeine: 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). Use the lowest effective dose for the shortest period of time. May produce drug dependence and has potential for abuse. Psychic dependence, physical dependence and tolerance may develop upon repeated administration; use with caution. May impair mental/physical abilities. ASA: Extreme caution in patients with peptic ulcer or coagulation abnormalities.

ADVERSE REACTIONS

Lightheadedness, dizziness, drowsiness, sedation, N/V, constipation, pruritus, skin reactions.

DRUG INTERACTIONS

May exhibit additive CNS depression with other narcotic analgesics, general anesthetics, tranquilizers, sedative hypnotics, or other CNS depressants (including alcohol); reduce dose of one or both agents. ASA: May enhance effects of anticoagulants. Inhibits effects of uricosuric agents.

PREGNANCY AND LACTATION

Safety not known in pregnancy, not for use in nursing.

MECHANISM OF ACTION

Dihydrocodeine: Semisynthetic narcotic analgesic; multiple actions, qualitatively similar to those of codeine. Principal action of therapeutic value is analgesia. ASA: Antipyretic-analgesic.

PHARMACOKINETICS

Distribution: Found in breast milk.

ASSESSMENT

Assess for severity of pain, drug hypersensitivity, peptic ulcer or coagulation abnormalities, or any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for possible psychic/physical dependence, respiratory depression, and other adverse reactions.

PATIENT COUNSELING

Instruct to take as ud. Inform about the risks/benefits of therapy. Advise patients that a genetic variation may lead to life-threatening or fatal respiratory depression or signs of overdose (eg, extreme sleepiness, confusion, shallow breathing). Advise caregivers of children receiving therapy to monitor for signs of respiratory depression. Instruct nursing mothers to monitor their infants for signs of dihydromorphine toxicity (eg, increased sleepiness, breastfeeding/breathing difficulties, limpness); instruct to seek immediate medical attention if these signs develop.

STORAGE

25°C (77°F).

Back to top