Norco 5/325 (acetaminophen/hydrocodone bitartrate) - Drug Summary

Actavis Pharma, Inc.

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Norco
(acetaminophen/hydrocodone bitartrate)

BOXED WARNING

Associated w/ cases of acute liver failure, at times resulting in liver transplant and death. Most cases of liver injury are associated w/ APAP use at doses >4000mg/day, and often involve >1 APAP-containing product.

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Moderate to Moderately Severe Pain

5mg/325mg:
Usual: 1 or 2 tabs q4-6h prn
Max: 8 tabs/day

7.5mg/325mg, 10mg/325mg:
Usual: 1 tab q4-6h prn
Max: 6 tabs/day

DOSING CONSIDERATIONS

Elderly
Start at lower end of dosing range

ADMINISTRATION

Oral route

HOW SUPPLIED

Tab: (Hydrocodone/APAP) 5mg/325mg*, 7.5mg/325mg*, 10mg/325mg* *scored

CONTRAINDICATIONS

Hypersensitivity to hydrocodone or acetaminophen.

WARNINGS/PRECAUTIONS

Increased risk of acute liver failure in patients w/ underlying liver disease. May cause serious skin reactions (eg, acute generalized exanthematous pustulosis, Stevens-Johnson syndrome, toxic epidermal necrolysis); d/c at the 1st appearance of skin rash or any other sign of hypersensitivity. Hypersensitivity and anaphylaxis reported; d/c

immediately if signs/symptoms occur. May produce dose-related respiratory depression and irregular/periodic breathing. Respiratory depressant effects and CSF pressure elevation capacity may be markedly exaggerated in the presence of head injury, other intracranial lesions, or a preexisting increase in intracranial pressure. May obscure clinical course of head injuries and acute abdominal conditions. Caution w/ hypothyroidism, Addison's disease, prostatic hypertrophy, urethral stricture, severe hepatic/renal impairment, or in elderly/debilitated. Suppresses cough reflex; caution w/ pulmonary disease and in postoperative use. Lab test interactions may occur. May be habit-forming.

ADVERSE REACTIONS

Acute liver failure, lightheadedness, dizziness, sedation, N/V.

DRUG INTERACTIONS

Increased risk of acute liver failure w/ alcohol. Additive CNS depression w/ other narcotics, antihistamines, antipsychotics, antianxiety agents, or other CNS depressants (eg, alcohol); reduce dose of one or both agents. Concomitant use w/ MAOIs or TCAs may increase the effect of either the antidepressant or hydrocodone.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Hydrocodone: Opioid analgesic and antitussive; has not been established. Action believed to be related to the existence of opiate receptors in the CNS. APAP: Nonopiate, nonsalicylate analgesic, and antipyretic; has not been established. Antipyretic activity is mediated through hypothalamic heat-regulating centers; inhibits prostaglandin synthetase.

PHARMACOKINETICS

Absorption: Hydrocodone: (10mg) C_{max}=23.6ng/mL; T_{max}=1.3 hrs. APAP: Rapid. **Distribution:** APAP: Found in breast milk. **Metabolism:** Hydrocodone: O-demethylation, N-demethylation, and 6-keto reduction. APAP: Liver (conjugation). **Elimination:** Hydrocodone: (10mg) $T_{1/2}$=3.8 hrs. APAP: Urine (85%, mostly glucuronide conjugate); $T_{1/2}$=1.25-3 hrs.

ASSESSMENT

Assess for history of hypersensitivity to drug, level of pain intensity, type of pain, patient's general condition and medical status, renal/hepatic impairment, pregnancy/nursing status, any other conditions where treatment is cautioned, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of hypersensitivity or anaphylaxis, serious skin reactions, acute liver failure, respiratory depression, elevations in CSF pressure, drug abuse/dependence/tolerance, and other adverse reactions. In patients w/ severe hepatic/renal disease, monitor effects w/ serial hepatic and/or renal function tests.

PATIENT COUNSELING

Instruct to look for APAP on package labels and not to use >1 APAP-containing product. Instruct to seek medical attention immediately upon ingestion of >4000mg/day of APAP, even if feeling well. Advise to d/c use and contact physician immediately if signs of allergy develop. Inform about signs of serious skin reactions. Inform that drug may impair mental/physical abilities, and to use caution if performing potentially hazardous tasks (eg, driving, operating machinery). Instruct to avoid alcohol and other CNS depressants. Inform that drug may be habit-forming; instruct to take only ud.

STORAGE

(5mg-325mg) 15-30°C (59-86°F). (7.5mg-325mg, 10mg-325mg) 20-25°C (68-77°F).

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