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RxList
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NORCO® 7.5/325
(hydrocodone bitartrate and acetaminophen)
NORCO® 10/325
(hydrocodone bitartrate and acetaminophen) Tablet

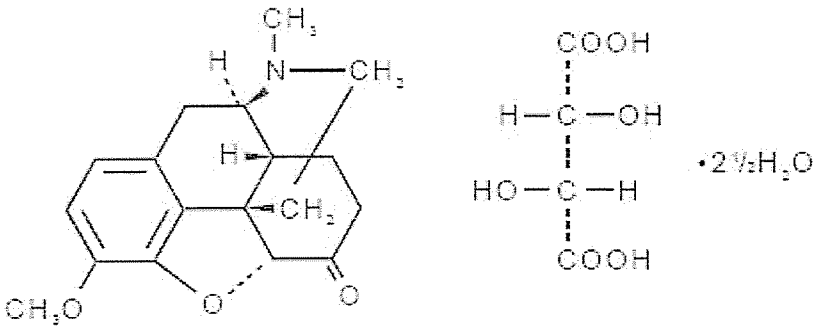
Norco

- Patient Information:
  Details with Side Effects

DRUG DESCRIPTION

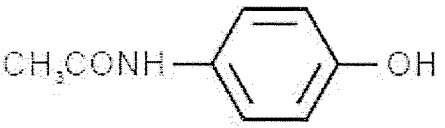
NORCO® (hydrocodone bitartrate and acetaminophen) is supplied in tablet form for oral administration.

Hydrocodone bitartrate is an opioid analgesic and antitussive and occurs as fine, white crystals or as a crystalline powder. It is affected by light. The chemical name is 4,5α-Epoxy-3-methoxy-17-methylmorphinan-6-one tartrate (1:1) hydrate (2:5). It has the following structural formula:



$C_{18}H_{21}NO_3 \cdot C_4H_6O_6 \cdot 2\frac{1}{2}H_2O$ M. W. = 494.49

Acetaminophen, 4′-Hydroxyacetanilide, a slightly bitter, white, odorless, crystalline powder, is a non-opiate, non-salicylate analgesic and antipyretic. It has the following structural formula:



$C_8H_9NO_2$ M. W. = 151.16

NORCO (hydrocodone bitartrate and acetaminophen) ®, for oral administration is available in the following strengths:

	Hydrocodone Bitartrate	Acetaminophen

NORCO® 7.5/325	7.5 mg	325 mg
NORCO® 10/325	10 mg	325 mg

In addition, each tablet contains the following inactive ingredients: croscarmellose sodium, crospovidone, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, and stearic acid; the 7.5 mg/325 mg tablets include FD&C Yellow #6 Aluminum Lake, the 10 mg/325 mg tablets include D&C Yellow #10 Aluminum Lake. Meets USP Dissolution Test 1.

What are the possible side effects of acetaminophen and hydrocodone?

Get emergency medical help if you have any of these **signs of an allergic reaction:** hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side effects:

- shallow breathing, slow heartbeat;
- feeling light-headed, fainting;
- confusion, fear, unusual thoughts or behavior;
- seizure (convulsions);
- problems with urination; or
- nausea, upper stomach pain, itching, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or...

Read All Potential Side Effects and See Pictures of Norco »

What are the precautions when taking hydrocodone bitartrate and acetaminophen (Norco)?

See also Warning section.

Before taking this medication, tell your doctor or pharmacist if you are allergic to it; or to other narcotics (such as morphine, codeine); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: brain disorders (such as head injury, tumor, seizures), breathing problems (such as asthma, sleep apnea, chronic obstructive pulmonary disease-COPD), kidney disease, liver disease, mental/mood disorders (such as confusion, depression), personal or family history of regular use/abuse of drugs/alcohol, stomach/intestinal problems (such as...

Read All Potential Precautions of Norco »

Last reviewed on RxList: 9/27/2010

Medical Editor: Charles Patrick Davis, MD, PhD

This monograph has been modified to include the generic and brand name in many instances.

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INDICATIONS

NORCO (hydrocodone bitartrate and acetaminophen) ® is indicated for the relief of moderate to moderately severe pain.

DOSAGE AND ADMINISTRATION

Dosage should be adjusted according to the severity of the pain and the response of the patient. However, it should be kept in mind that tolerance to hydrocodone can develop with continued use and that the incidence of untoward effects is dose related.

The usual adult dosage is one tablet every four to six hours as needed for pain. The total daily dose should not exceed 6 tablets.

HOW SUPPLIED

NORCO® 7.5/325 is available as capsule-shaped, light orange tablets bisected on one side and debossed with "NORCO 729" on the other side. Each tablet contains 7.5 mg hydrocodone bitartrate and 325 mg acetaminophen. They are supplied as follows:

Bottles of 30
Bottles of 100
Bottles of 500

NORCO® 10/325 is available as capsule-shaped, yellow tablets bisected on one side and debossed with "NORCO 539" on the other side. Each tablet contains 10 mg hydrocodone bitartrate and 325 mg acetaminophen. They are supplied as follows:

Bottles of 100
Bottles of 500

Store at controlled room temperature 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container with a child-resistant closure.

Watson Pharma, Inc.
A Subsidiary of Watson Pharmaceuticals, Inc., Corona CA 92880 USA
Revised: April 2003 FDA rev date: April 2003

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SIDE EFFECTS

The most frequently reported adverse reactions are lightheadedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include:

Central Nervous System: Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence, mood changes.

Gastrointestinal System: Prolonged administration of NORCO (hydrocodone bitartrate and acetaminophen) ® may produce constipation.

Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported with opiates.

Respiratory Depression: Hydrocodone bitartrate may produce dose-related respiratory depression by acting directly on the brain stem respiratory centers (see OVERDOSAGE).

Special Senses: Cases of hearing impairment or permanent loss have been reported predominantly in patients with chronic overdose.

Dermatological: Skin rash, pruritus.

The following adverse drug events may be borne in mind as potential effects of acetaminophen: allergic reactions, rash, thrombocytopenia, agranulocytosis. Potential effects of high dosage are listed in the OVERDOSAGE section.

DRUG ABUSE AND DEPENDENCE

Controlled Substance: NORCO (hydrocodone bitartrate and acetaminophen) ® is classified as a Schedule III controlled substance.

Abuse and Dependence: Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore, this product should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when NORCO (hydrocodone bitartrate and acetaminophen) ® is used for a short time for the treatment of pain.

Physical dependence, the condition in which continued administration of the drug is required to prevent the appearance of a withdrawal syndrome, assumes clinically significant proportions only after several weeks of continued narcotic use, although some mild degree of physical dependence

may develop after a few days of narcotic therapy. Tolerance, in which increasingly large doses are required in order to produce the same degree of analgesia, is manifested initially by a shortened duration of analgesic effect, and subsequently by decreases in the intensity of analgesia. The rate of development of tolerance varies among patients.

Read the Norco (hydrocodone bitartrate and acetaminophen) Side Effects Center for a complete guide to possible side effects

Learn More »

DRUG INTERACTIONS

Patients receiving other narcotics, antihistamines, antipsychotics, antianxiety agents, or other CNS depressants (including alcohol) concomitantly with NORCO (hydrocodone bitartrate and acetaminophen) ® may exhibit an additive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced.

The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone.

Drug/Laboratory Test Interactions

Acetaminophen may produce false-positive test results for urinary 5-hydroxyindoleacetic acid.

Read the Norco Drug Interactions Center for a complete guide to possible interactions

Learn More »

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WARNINGS

Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing.

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

PRECAUTIONS

General

Special Risk Patients: As with any narcotic analgesic agent, NORCO (hydrocodone bitartrate and acetaminophen) ® should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.

Cough Reflex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when NORCO (hydrocodone bitartrate and acetaminophen) ® is used postoperatively and in patients with pulmonary disease.

Laboratory Tests

In patients with severe hepatic or renal disease, effects of therapy should be monitored with serial liver and/or renal function tests.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No adequate studies have been conducted in animals to determine whether hydrocodone or

acetaminophen have a potential for carcinogenesis, mutagenesis, or impairment of fertility.

Pregnancy

Teratogenic Effects: Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. NORCO (hydrocodone bitartrate and acetaminophen) ® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose. There is no consensus on the best method of managing withdrawal.

Labor and Delivery

As with all narcotics, administration of this product to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers

Acetaminophen is excreted in breast milk in small amounts, but the significance of its effects on nursing infants is not known. It is not known whether hydrocodone is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from hydrocodone and acetaminophen, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical studies of hydrocodone bitartrate 5 mg and acetaminophen 500 mg did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Hydrocodone and the major metabolites of acetaminophen are known to be substantially excreted by the kidney. Thus the risk of toxic reactions may be greater in patients with impaired renal function due to the accumulation of the parent compound and/or metabolites in the plasma. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Hydrocodone may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of hydrocodone bitartrate and acetaminophen tablets and observed closely.

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