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UNBP1514 06/15

Theracodophen-Low-90 Hydrocodone Bitartrate and Acetaminophen

NDC 53746-111-05

Hydrocodone
Bitartrate and
Acetominophen
Tablets, USP

Multiple Strengths:
Do not dispense unless
strength is stated.

Rx only 500 TABLETS

Each tablet contains:

hydrocodone bitartrate	5 mg
acetaminophen	500 mg

Usual adult dosage: See package insert.

Store at 25 degrees C (77 degrees F); excursions permitted to 15 degrees - 30 degrees C (59 - 86 degrees F). [See USP Controlled Room Temperature].

Dispense in tight, light-resistant container as defined in the USP.

Protect from light.

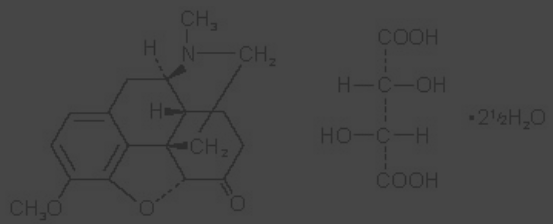
Do not accept if inner seal is broken or missing.

Manufactured by: Amneal Pharmaceticals of NY
Hauppauge, NY 11788

Distributed by: Amneal Pharmaceuticals
Glasgow, KY 42141

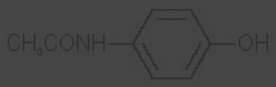
Hydrocodone bitartrate and acetaminophen is supplied in tablet form for oral administration.

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:



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

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



$C_8H_9NO_2$ MW=151.16

Hydrocodone Bitartrate and Acetaminophen Tablets USP for oral administration are available in a variety of strengths as described in the following table.

Strength	Hydrocodone Bitartrate	Acetaminophen
2.5 mg/500mg	2.5mg	500mg
5mg/500mg	5mg	500mg
7.5mg/325mg	7.5mg	325mg
7.5mg/500mg	7.5mg	500mg
7.5mg/650mg	7.5mg	650mg
7.5mg/750mg	7.5mg	750mg
10mg/325mg	10mg	325mg
10mg/500mg	10mg	500mg
10mg/650mg	10mg	650mg
10mg/660mg	10mg	660mg
10mg/750mg	10mg	750mg

In addition, each tablet contains the following inactive ingredients:

In addition, each tablet contains the following inactive ingredients: anhydrous lactose, croscarmellose sodium, crospovidone, magnesium stearate, microcrystalline cellulose, povidone, starch and stearic acid; except the 7.5 mg/325 mg, 10 mg/325 mg and 10 mg/500 mg tablets do not contain anhydrous lactose. The 7.5 mg/325 mg tablets include FD and C Yellow Number 6 Aluminum Lake; the 7.5 mg/650 mg tablets include FD and C Red Number 40 Aluminum Lake; the 10 mg/325 mg and 10 mg/750 mg tablets include D and C Yellow Number 10 Aluminum Lake; the 10 mg/500 mg include FD and C Blue Number 2 Aluminum Lake; and the 10 mg/650 mg tablets include FD and C Blue Number 1 Aluminum Lake and D and C Yellow number 10 Aluminum Lake. Meets USP Dissolution Test 1.

Hydrocodone is a semisynthetic narcotic analgesic and antitussive with multiple actions qualitatively similar to those of codeine. Most of these involve the central nervous system and smooth muscle. The precise mechanism of action of hydrocodone and other opiates is not known, although it is believed to relate to the existence of opiate receptors in the central nervous system. In addition to analgesia, narcotics may produce drowsiness, changes in mood and mental clouding.

The analgesic action of acetaminophen involves peripheral influences, but the specific mechanism is as yet undetermined. Antipyretic activity is mediated through hypothalamic heat regulating centers. Acetaminophen inhibits prostaglandin synthetase. Therapeutic doses of acetaminophen have negligible effects on the cardiovascular or respiratory systems; however, toxic doses may cause circulatory failure and rapid, shallow breathing.

Pharmacokinetics: The behavior of the individual components is described below.

Hydrocodone: Following a 10 mg oral dose of hydrocodone administered to five adult male subjects, the mean peak concentration was 23.6 ± 5.2 ng/mL. Maximum serum levels were achieved at 1.3 ± 0.3 hours and the half-life was determined to be 3.8 ± 0.3 hours. Hydrocodone exhibits a complex pattern of metabolism including O-demethylation, N-demethylation and 6-keto reduction to the corresponding 6-α- and 6-β-hydroxymetabolites.
See OVERDOSAGE for toxicity information.

Acetaminophen: Acetaminophen is rapidly absorbed from the gastrointestinal tract and is distributed throughout most body tissues. The plasma half-life is 1.25 to 3 hours, but may be increased by liver damage and following overdosage. Elimination of acetaminophen is principally by liver metabolism (conjugation) and subsequent renal excretion of metabolites. Approximately 85% of an oral dose appears in the urine within 24 hours of administration, most as the glucuronide conjugate, with small amounts of other conjugates and unchanged drug.
See OVERDOSAGE for toxicity information.

Hydrocodone and acetaminophen tablets are indicated for the relief of moderate to moderately severe pain.

This product should not be administered to patients who have previously exhibited hypersensitivity to hydrocodone or acetaminophen. Patients known to be hypersensitive to other opioids may exhibit cross-sensitivity to hydrocodone.

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.

General:
Special Risk Patients: As with any narcotic analgesic agent, hydrocodone bitartrate and acetaminophen tablets 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 hydrocodone bitartrate and acetaminophen tablets are used postoperatively and in patients with pulmonary disease.

Information for Patients: Hydrocodone, like all narcotics, may impair mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.

Alcohol and other CNS depressants may produce an additive CNS depression, when taken with this combination product, and should be avoided.

Hydrocodone may be habit-forming. Patients should take the drug only for as long as it is prescribed, in the amounts prescribed, and no more frequently than prescribed.

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

Drug Interactions: Patients receiving narcotics, antihistamines, antipsychotics, antianxiety agents, or other CNS depressants (including alcohol) concomitantly with hydrocodone bitartrate and acetaminophen tablets 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.

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. Hydrocodone bitartrate and acetaminophen tablets 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, 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. 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 hydrocodone bitartrate and acetaminophen tablets 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 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.

Controlled Substance: Hydrocodone Bitartrate and Acetaminophen Tablets are 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 hydrocodone bitartrate and acetaminophen tablets are 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.

Following an acute overdosage, toxicity may result from hydrocodone or acetaminophen.

Signs and Symptoms
Hydrocodone: Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.

Acetaminophen: In acetaminophen overdosage: dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma and thrombocytopenia may also occur.

Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams, or fatalities with less than 15 grams.

Treatment: A single or multiple overdose with hydrocodone and acetaminophen is a potentially lethal polydrug overdose, and consultation with a regional poison control center is recommended.

Immediate treatment includes support of cardiorespiratory function and measures to reduce drug absorption. Vomiting should be induced mechanically, or with syrup of ipecac, if the patient is alert (adequate pharyngeal and laryngeal reflexes). Oral activated charcoal (1 g/kg) should follow gastric emptying. The first dose should be accompanied by an appropriate cathartic. If repeated doses are used, the cathartic might be included with alternate doses as required. Hypotension is usually hypovolemic and should respond to fluids. Vasopressors and other supportive measures should be employed as indicated. A cuffed endotracheal tube should be inserted before gastric lavage of the unconscious patient and, when necessary, to provide assisted respiration.

Meticulous attention should be given to maintaining adequate pulmonary ventilation. In severe cases of intoxication, peritoneal dialysis, or preferably hemodialysis may be considered. If hypoprothrombinemia occurs due to acetaminophen overdose, vitamin K should be administered intravenously.

Naloxone, a narcotic antagonist, can reverse respiratory depression and coma associated with opioid overdose. Naloxone hydrochloride 0.4 mg to 2 mg is given parenterally. Since the duration of action of hydrocodone may exceed that of the naloxone, the patient should be kept under continuous surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. A narcotic antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression.

If the dose of acetaminophen may have exceeded 140 mg/kg, acetylcysteine should be administered as early as possible. Serum acetaminophen levels should be obtained, since levels four or more hours following ingestion help predict acetaminophen toxicity. Do not await acetaminophen assay results before initiating treatment. Hepatic enzymes should be obtained initially, and repeated at 24-hour intervals.

Methemoglobinemia over 30% should be treated with methylene blue by slow intravenous administration.

The toxic dose for adults for acetaminophen is 10 g. 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.

2.5 mg/500 mg **5 mg/500 mg**	The usual adult dosage is one or two tablets every four to six hours as needed for pain. The total daily dose should not exceed 8 tablets.
7.5 mg/325 mg **7.5 mg/500 mg** **7.5 mg/650 mg**	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.
7.5 mg/750 mg	The usual adult dosage is one tablet every four to six hours

	as needed for pain. The total daily dose should not exceed 5 tablets.
10 mg/325 mg **10 mg/500 mg** **10 mg/650 mg** **10 mg/660 mg**	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.
10 mg/750 mg	The usual adult dosage is one tablet every four to six hours as needed for pain. The total daily dose should not exceed 5 tablets.

Hydrocodone Bitartrate and Acetominophen Tablets USP are available in the following strengths:

2.5 mg/500 mg	2.5 mg hydrocodone bitartrate and 500 mg acetaminophen, oblong, white tablets bisected on one side and debossed with WATSON 388on the other side, supplied in bottles of 100.
5 mg/500 mg	5 mg hydrocodone bitartrate and 500 mg acetaminophen, capsule-shaped, white tablets bisected on one side and debossed with WATSON 349 on the other side, supplied in bottles of 100 and 500.
7.5 mg/325 mg	7.5 mg hydrocodone bitartrate and 325 mg acetaminophen, capsule-shaped, light orange tablets bisected on one side and debossed with WATSON 3203 on the other side, supplied in bottles of 100.
7.5 mg/500 mg	7.5 mg hydrocodone bitartrate and 500 mg acetaminophen, capsule-shaped, white tablets bisected on one side and debossed with WATSON 385on the other side, supplied in bottles of 100 and 500.
7.5 mg/650 mg	7.5 mg hydrocodone bitartrate and 650 mg acetaminophen, capsule-shaped, pink tablets bisected on one side and debossed with WATSON 502 on the other side, supplied in bottles of 100 and 500.
7.5 mg/750 mg	7.5 mg hydrocodone bitartrate and 750 mg acetaminophen, capsule-shaped, white tablets bisected on one side and debossed with WATSON 387 on the other side, supplied in bottles of 100 and 500.
10 mg/325 mg	10 mg hydrocodone bitartrate and 325 mg acetaminophen, capsule-shaped, yellow tablets bisected on one side and debossed with WATSON 853 on the other side, supplied in bottles of 100 and 500.
10 mg/500 mg	10 mg hydrocodone bitartrate and 500 mg acetaminophen, capsule-shaped, blue tablets bisected on one side and debossed with WATSON 540 on the other side, supplied in bottles of 100 and 500.
10 mg/650 mg	10 mg hydrocodone bitartrate and 650 mg acetaminophen, capsule-shaped, light green tablets bisected on one side and debossed with WATSON 503 on the other side, supplied in bottles of 100 and 500.

10 mg/660 mg 10 mg hydrocodone bitartrate and 660 mg acetaminophen, oval-shaped, white tablets bisected on one side and debossed with WATSON 517 on the other side, supplied in bottles of 100 and 500.

10 mg/750 mg 10 mg hydrocodone bitartrate and 750 mg acetaminophen, capsule-shaped, yellow tablets bisected on one side and debossed with WATSON 3228 on the other side, supplied in bottles of 100.

Store at 20 degrees - 25 degrees C (68 degrees - 77 degrees F). [See USP controlled room temperature.]

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

Watson Laboratories, Inc. Revised: March 2007
Corona, CA 92880 USA 0907B
14715

A Convenience Packed Medical Food and Drug

Theracodophen-Low-90

Physician Therapeutics

- Theramine 90 Capsules

- Hydrocodone 5 mg plus
Acetaminophen 500 mg 30 Tablets

Rx Only

No Refills Without Physician Authorization NDC Number 68405-298-36 of this co-pack

Theracodephen-Low-90
Convenience Pack

Hydrocodone-Acetaminophen: Why is this medication prescribed?

Hydrocodone-Acetaminophen is a combination of a narcotic (hydrocodone) and a non-narcotic (acetaminophen) used to relieve moderate to severe pain. Hydrocodone works by binding to opioid receptors in the brain and spinal cord, and acetaminophen decreases the formation of prostaglandins, therefore relieving pain.

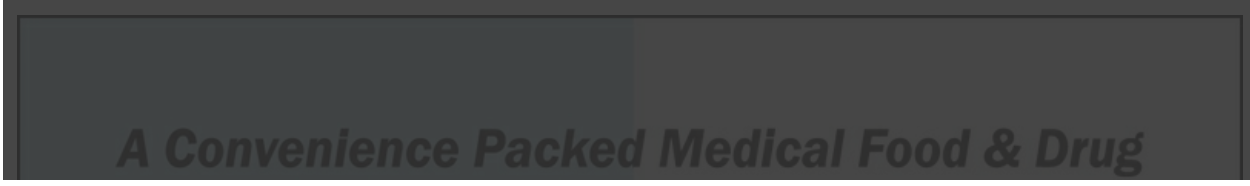
Theramine: Why is this medication prescribed?

Theramine is a Medical Food product designed to aid in the nutritional management of pain syndromes.

Theramine stimulates production of serotonin, GABA, norepinephrine, nitric oxide, and acetylcholine, the neurotransmitters that are involved in pain disorders. If the timing and secretion of these neurotransmitters are effectively modulated, acute, and chronic pain disorders are more effectively managed. Theramine provides L-arginine at a low dose along with choline and L-glutamine to inhibit the NMDA and opioid receptors.

Theramine aids in the nutritional management of serotonin, GABA, and acetylcholine production deficiencies in patients with pain sydromes

NDC Number 68405-298-36



Theracodophen-Low-90™

- **Theramine™ 90 Capsules**
- **Hydrocodone 5 mg + Acetaminophen 500 mg 30 Tablets**

Rx Only

No Refills Without
Physician Authorization

NDC# 68405-298-36
of this co-pack

THERACODOPHEN-LOW-90

hydrocodone bitartrate and acetaminophen tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:68405-298
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCODONE BITARTRATE (HYDROCODONE)	HYDROCODONE BITARTRATE	5 mg
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE	
CROSCARMELLOSE SODIUM	
CROSPOVIDONE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONE	
STEARIC ACID	

Product Characteristics			
Color	white	**Score**	2 pieces

Shape	OVAL	Size	18mm
Flavor		Imprint Code	WATSON;349
Contains			

Packaging

#	Item Code	Package Description
1	NDC:68405-298-36	1 BOTTLE (BOTTLE) in 1 PACKAGE
1		30 TABLET (TABLET) in 1 BOTTLE

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040729	12/11/2009	

Labeler - Physician Therapeutics LLC (931940964)

Establishment

Name	Address	ID/FEI	Operations
Targeted Medical Pharma, Inc.		126962740	manufacture, relabel, repack

Establishment

Name	Address	ID/FEI	Operations
Bryant Ranch Prepack		171714327	manufacture, repack

Revised: 03/2010

Physician Therapeutics LLC

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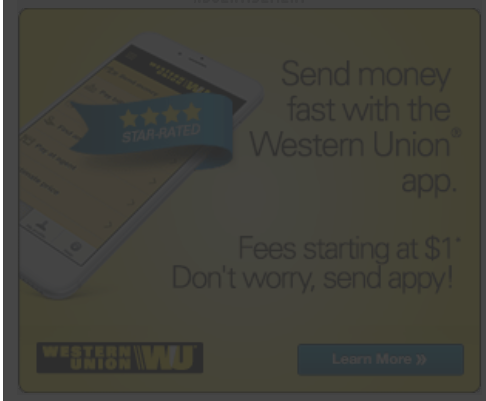

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- *Other brands:* ***Norco***, ***Vicodin***, ***Lortab***, ***Vicodin ES***, ***More (12) »***

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- **Pain**
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DRUG STATUS

Availability
Prescription only

Pregnancy Category
Risk cannot be ruled out

CSA Schedule
High potential for abuse

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Drug Class

Narcotic analgesic combinations

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narcotic analgesic combinations
Percocet, **Norco**, **Suboxone**, **Vicodin**, **Lortab**, **Tylenol with Codeine #3**

Back Pain
tramadol, **naproxen**, **Cymbalta**, **aspirin**, **ibuprofen**, **Norco**, **diclofenac**, More...

Pain
tramadol, **oxycodone**, **acetaminophen**, **naproxen**, **Tylenol**, **aspirin**, **ibuprofen**, More...

Cough
Benadryl, **benzonatate**, **Dilaudid**, **diphenhydramine**, **guaifenesin**, **Mucinex**, **codeine**, **hydromorphone**, More...

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