HYDROCODONE BITARTRATE AND ACETAMINOPHEN- hydrocodone bitartrate and acetaminophen tablet
Apotheca, Inc.

HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLET USP 10MG/325MG CSII

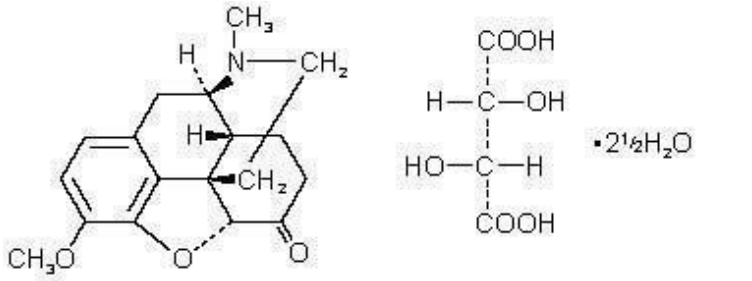
DESCRIPTION

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

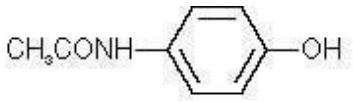
The chemical name is

4 5a Epoxy 3 methoxy 17 methylmorphinan 6 one tartrate1 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=494.50

Acetaminophen, 4 Hydroxyacetanilide, a slightly bitter white odorless crystalline powder is a nonopiate 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 the following strengths

- 10mg 325mg 10mg Hydrocodone Bitartrate USP 325mg Acetaminophen USP

Discontinued the following strengths

- 10mg 500mg 10mg Hydrocodone Bitartrate USP 500mg Acetaminophen USP
- 10mg 650mg 10mg Hydrocodone Bitartrate USP 650mg Acetaminophen USP

BOXED WARNING

HEPATOTOXICITY
Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product.

CLINICAL PHARMACOLOGY

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, Ndemethylation and 6-keto reduction to the corresponding 6-a- and 6-b-hydroxy-metabolites. **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**

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

WARNINGS

Hepatotoxicity

Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing product. The excessive intake of acetaminophen may be intentional to cause self-harm or unintentional as patients attempt to obtain more pain relief or unknowingly take other acetaminophen-containing products

The risk of acute liver failure is higher in individuals with underlying liver disease and in individuals who ingest alcohol while taking acetaminophen

Instruct patients to look for acetaminophen or APAP on package labels and not to use more than one product that contains acetaminophen. Instruct patients to seek medical attention immediately upon ingestion of more than 4000 milligrams of acetaminophen per day, even if they feel well

Serious skin reactions

Rarely, acetaminophen may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity

Hypersensitivity anaphylaxis

There have been post-marketing reports of hypersensitivity and anaphylaxis associated with use of acetaminophen. Clinical signs include swelling of the face, mouth, and throat, respiratory distress, urticaria, rash, pruritis, and vomiting. There were infrequent reports of life-threatening anaphylaxis requiring emergency medical attention. Instruct patients to discontinue Hydrocodone Bitartrate and Acetaminophen Tablets, USP immediately and seek medical care if they experience these symptoms. Do not prescribe Hydrocodone Bitartrate and Acetaminophen Tablets, USP for patients with acetaminophen allergy

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 preexisting 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

Misuse, Abuse, and Diversion of Opioids

Hydrocodone bitartrate and acetaminophen tablets contain hydrocodone, an opioid agonist, and is a Schedule III controlled substance. Opioid agonists have the potential for being abused and are sought by abusers and people with addiction disorders, and are subject to diversion.

Hydrocodone bitartrate and acetaminophen tablets can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing hydrocodone bitartrate and acetaminophen tablets in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion (see **DRUG ABUSE AND DEPENDENCE).**

PRECAUTIONS

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 the 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 other narcotic analgesics, 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 and 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

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 hydrocodone bitartrate and acetaminophen tablets 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 and acetaminophen tablets 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

ADVERSE REACTIONS

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 the brain stem respiratory center (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

Misuse, Abuse, and Diversion of Opioids

Hydrocodone bitartrate and acetaminophen tablets contain hydrocodone, an opioid agonist, and is a Schedule II controlled substance. Hydrocodone bitartrate and acetaminophen, and other opioids, used in analgesia can be abused and are subject to criminal diversion.

Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Drug addiction is a treatable disease utilizing a multidisciplinary approach, but relapse is common.

“Drug seeking” behavior is very common in addicts and drug abusers. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated “loss” of prescriptions, tampering with prescriptions and reluctance to provide prior medical records or contact information for other treating physician(s). “Doctor shopping” to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction.

Abuse and addiction are separate and distinct from physical dependence and tolerance. Physical dependence usually assumes clinically significant dimensions only after several weeks of continued opioid use, although a mild degree of physical dependence may develop after a few days of opioid 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. Physicians should be aware that abuse of opioids can occur in the absence of true addiction and is characterized by misuse for non-medical purposes, often in combination with other psychoactive substances. Hydrocodone bitartrate and acetaminophen, like other opioids, may be diverted for non-medical use. Record-keeping of prescribing information, including quantity, frequency, and renewal requests is strongly advised.

Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs

OVERDOSAGE

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 AND ADMINISTRATION

Dosage should be adjusted according to the severity of the pain and 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 for Hydrocodone Bitartrate and Acetaminophen Tablets USP is

10mg/325mg	The usual adult dosage is **one tablet** every four to six hours as needed for pain. The total daily dosage should not exceed **6 tablets**
10mg/500mg	The usual adult dosage is **one tablet** every four to six hours as needed for pain. The total daily dosage should not exceed **6 tablets**
10mg/650mg	The usual adult dosage is **one tablet** every four to six hours as needed for pain. The total daily dosage should not exceed **6 tablets**

HOW SUPPLIED

Hydrocodone Bitartrate and Acetaminophen tablets, USP are available in the following strengths:
10mg 325mg 10mg of Hydrocodone Bitartrate and 325mg of Acetaminophen.White to off white, scored, oblong biconvex tablets, debossed
IP110 on obverse and bisected on the reverse
They are supplied as follows

- 12634-144-78 Bottle of 12
- 12634-144-85 Bottle of 15
- 12634-144-79 Bottle of 25
- 12634-144-91 Blister Pack UD of 1
- 12634-144-61 Blister Pack Card 10
- 12634-144-52 Blister Pack Card 12
- 12634-144-55 Blister Pack Card 15

10mg 500mg 10mg of Hydrocodone Bitartrate and 500mg of Acetaminophen.Capsule-shaped, blue tablets bisected on one side and debossed
with Watson540 on the other side
DISCONTINUED

- 12634-978-95 Bottle of 5
- 12634-978-00 Bottle of 10
- 12634-978-85 Bottle of 15
- 12634-978-71 Bottle of 30
- 12634-978-91 Blister Pack UD of 1
- 12634-978-55 Blister Pack Card of 15

10mg 650mg 10mg of Hydrocodone Bitartrate and 650mg of Acetaminophen. White to off white, scored, oblong, biconvex tablets, debossed
IP114 on obverse, a bisected on the reverse
DISCONTINUED

- 12634-256-79 Bottle of 5
- 12634-256-50 Bottle of 50
- 12634-256-91 Blister Pack UD of 1

Storage

Dispense in a tight, light-resistant container as defined in the USP with a child-resistant closure.

Store at 20 - 25°C (68 - 77°F). (See USP for Controlled Room Temperature).

PACKAGE LABEL AND PRINCIPAL DISPLAY PANEL

Hydocodone Bitartrate
And Acetaminophen 10 325mg

25 Tablets

NDC 12634-144-79 CII

COMPARE TO NORCO

Rx Only

Repackaged and Distributed by
Apotheca, Inc.
Phoenix, AZ 85006

A Schedule CIII Controlled Drug Substance - DISCONTINUED 12-31-2014
NDC 12634-978-55 Card 15 Tablets
Each Tablet Contains
Hydocodone Bitartrate 10 mg
Acetaminophen 500 mg
Usual Adult Dosage
See insert for full prescribing information
One tablet every four to six hours, as needed for pain. Total daily dosage should not exceed six tablets
Repackaged and Distributed by

Apotheca, Inc
Phoenix, AZ 85006

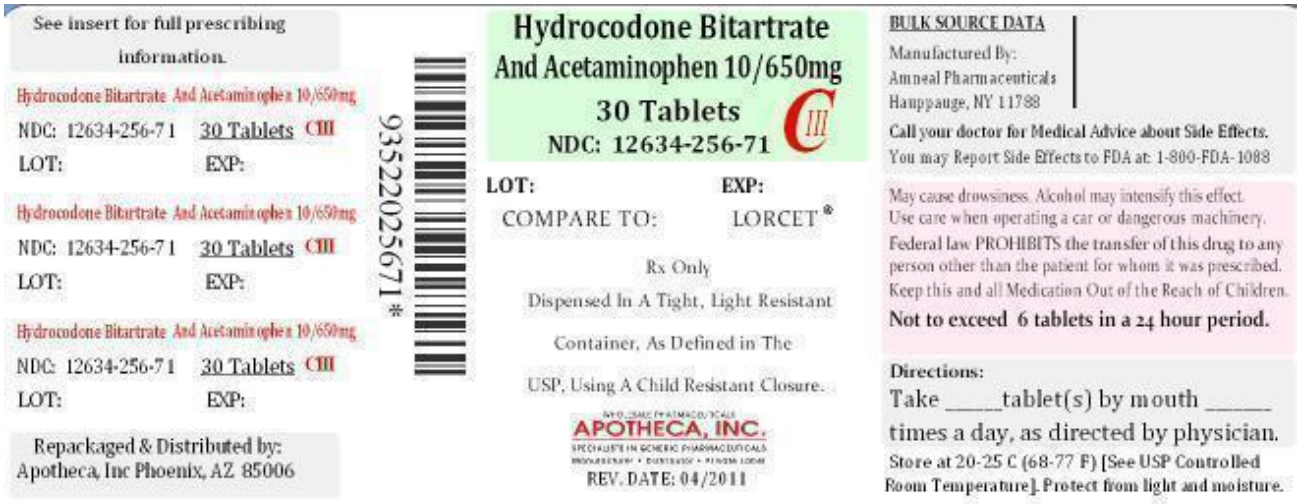
Hydrocodone Bitartrate

And Acetaminophen 10 650mg 30 Tablets CIII - DISCONTINUED 12-31-2013

NDC 12634-256-71

COMPARE TO LORCET

Rx Only



HYDROCODONE BITARTRATE AND ACETAMINOPHEN

hydrocodone bitartrate and acetaminophen tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:12634-144(NDC:53746-110)
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCODONE BITARTRATE (UNII: NO70W886KK) (HYDROCODONE - UNII:6YKS4Y3WQ7)	HYDROCODONE BITARTRATE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSPOVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white (white-to off white)	**Score**	2 pieces

Shape	CAPSULE (oblong, biconvex tablets)	**Size**	15mm
Flavor		**Imprint Code**	IP;110
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12634-144-91	1 in 1 BLISTER PACK		
2	NDC:12634-144-61	10 in 1 BLISTER PACK		
3	NDC:12634-144-52	12 in 1 BLISTER PACK		
4	NDC:12634-144-55	15 in 1 BLISTER PACK		
5	NDC:12634-144-78	12 in 1 BOTTLE		
6	NDC:12634-144-85	15 in 1 BOTTLE		
7	NDC:12634-144-79	25 in 1 BOTTLE		
8	NDC:12634-144-71	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040746	03/20/2009	

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

hydrocodone bitartrate and acetaminophen tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:12634-978(NDC:0591-0540)
Route of Administration	ORAL	**DEA Schedule**	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCODONE BITARTRATE (UNII: NO70W886KK) (HYDROCODONE - UNII:6YKS4Y3WQ7)	HYDROCODONE BITARTRATE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	blue (blue)	**Score**	2 pieces

Shape	CAPSULE (capsule-shape)	**Size**	15mm
Flavor		**Imprint Code**	watson;540
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12634-978-91	1 in 1 BLISTER PACK		
2	NDC:12634-978-55	15 in 1 BLISTER PACK		
3	NDC:12634-978-95	5 in 1 BOTTLE, PLASTIC		
4	NDC:12634-978-00	10 in 1 BOTTLE, PLASTIC		
5	NDC:12634-978-85	15 in 1 BOTTLE, PLASTIC		
6	NDC:12634-978-71	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040148	07/01/2008	12/31/2014

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

hydrocodone bitartrate and acetaminophen tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:12634-256(NDC:53746-114)
Route of Administration	ORAL	**DEA Schedule**	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCODONE BITARTRATE (UNII: NO70W886KK) (HYDROCODONE - UNII:6YKS4Y3WQ7)	HYDROCODONE BITARTRATE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (white to off white)	**Score**	2 pieces
Shape	CAPSULE (oblong, biconvex tablets)	**Size**	18mm
Flavor		**Imprint Code**	IP;114

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12634-256-91	1 in 1 BLISTER PACK		
2	NDC:12634-256-79	25 in 1 BOTTLE, PLASTIC		
3	NDC:12634-256-50	50 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040757	03/20/2009	12/31/2013

Labeler - Apotheca, Inc. (051457844)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca, Inc.		051457844	repack(12634-144, 12634-978, 12634-256)

Revised: 4/2010 Apotheca, Inc.