

ZAMICET- hydrocodone bitartrate and acetaminophen solution
Pharmaceutical Associates, Inc.

Zamicet® CII
(hydrocodone bitartrate and acetaminophen oral solution)
10 mg/325 mg per 15 mL

Rx ONLY

Hepatotoxicity

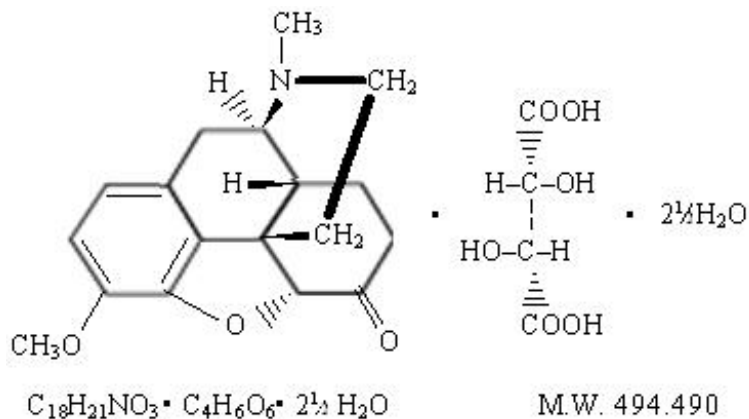
Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing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

DESCRIPTION

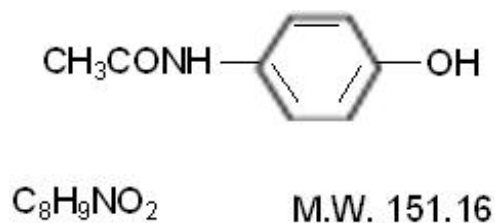
Zamicet® (hydrocodone bitartrate and acetaminophen oral solution) is supplied in liquid form for oral administration.

Warning: May be habit forming (see PRECAUTIONS, Information for Patients, and DRUG ABUSE AND DEPENDENCE).

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



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:



Zamicet® contains:

	Per 7.5 mL	Per 15 mL
Hydrocodone bitartrate	5 mg	10 mg
Acetaminophen	163 mg	325 mg
Alcohol	6.7%	6.7%

In addition Zamicet® contains the following inactive ingredients: citric acid, edetate disodium, glycerin, methylparaben, propylene glycol, purified water, saccharin sodium, sorbitol solution, sucrose, with D&C Yellow No. 10 as coloring and natural and artificial flavoring.

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, 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.

INDICATIONS AND USAGE

Zamicet® (hydrocodone bitartrate and acetaminophen oral solution) is 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, acetaminophen, or any other component of this product.

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 included swelling of the face, mouth, and throat, respiratory distress, urticaria, rash, pruritus, and vomiting. There were infrequent reports of life-threatening anaphylaxis requiring emergency medical attention. Instruct patients to discontinue Zamicet[®] immediately and seek medical care if they experience these symptoms. Do not prescribe Zamicet[®] for patients with acetaminophen allergy.

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.

Infants may have increased sensitivity to the respiratory depressant effects of opioids (see PRECAUTIONS, Pediatric Use). If use of hydrocodone bitartrate and acetaminophen oral solution in such patients is contemplated, it should be administered cautiously, in substantially reduced initial doses, by personnel experienced in administering opioids to infants, and with intensive monitoring.

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

Zamicet[®] contains hydrocodone, an opioid agonist, and is a Schedule II 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.

Zamicet[®] can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing Zamicet[®] 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, Zamicet[®] 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 Zamicet[®] is used postoperatively and in patients with pulmonary disease.

Information for Patients/Caregivers

- Do not take Zamicet[®] if you are allergic to any of its ingredients.
- If you develop signs of allergy such as a rash or difficulty breathing stop taking Zamicet[®] and contact your healthcare provider immediately.
- Do not take more than 4000 milligrams of acetaminophen per day. Call your doctor if you took more than the recommended dose.

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. Such tasks should be avoided while taking this product.

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.

Physicians should instruct patients and caregivers to read the patient information leaflet, which appears as the last section of the labeling.

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 Zamicet[®] 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 has a potential for carcinogenesis, mutagenesis, or impairment of fertility.

Hydrocodone has not demonstrated mutagenic potential using the Ames Salmonella-Microsomal Activation test, the Basc test on *Drosophila* germ cells, and the Micronucleus test on mouse bone marrow.

No adequate studies have been conducted in animals to determine whether acetaminophen has a potential for carcinogenesis, mutagenesis, or impairment of fertility.

Acetaminophen has not demonstrated mutagenic potential using the Ames Salmonella-Microsomal Activation test, the Basc test on *Drosophila* germ cells, and the Micronucleus test on mouse bone marrow.

Pregnancy

Teratogenic Effects

Pregnancy Category C

There are no adequate and well controlled studies in pregnant women. Zamicet[®] 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. These signs usually appear during the first few days of life. 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

Narcotic analgesics cross the placental barrier. The closer to delivery and the larger the dose used, the greater the possibility of respiratory depression in the newborn. Narcotic analgesics should be avoided during labor if delivery of a premature infant is anticipated. If the mother has received narcotic analgesics during labor, newborn infants should be observed closely for signs of respiratory depression. Resuscitation may be required (see OVERDOSAGE). The effect of hydrocodone, if any, on the later growth, development, and functional maturation of the child is unknown.

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 the pediatric population below the age of two years have not been established. Use of hydrocodone bitartrate and acetaminophen in the pediatric population is supported by the evidence from adequate and well controlled studies of hydrocodone and acetaminophen combination products in adults with additional data which support the development of metabolic pathways in children two years of age and over (see DOSAGE AND ADMINISTRATION for pediatric dosage information).

Geriatric Use

Clinical studies of hydrocodone bitartrate and acetaminophen oral solution 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 oral solution and observed closely.

ADVERSE REACTIONS

Potential effects of high dosage are also listed in the OVERDOSAGE section.

Cardio-renal: Bradycardia, cardiac arrest, circulatory collapse, renal toxicity, renal tubular necrosis, hypotension.

Central Nervous System/Psychiatric: Anxiety, dizziness, drowsiness, dysphoria, euphoria, fear, general malaise, impairment of mental and physical performance, lethargy, light-headedness, mental clouding, mood changes, psychological dependence, sedation, somnolence progressing to stupor or coma.

Endocrine: Hypoglycemic coma.

Gastrointestinal System: Abdominal pain, constipation, gastric distress, heartburn, hepatic necrosis, hepatitis, occult blood loss, nausea, peptic ulcer, and vomiting.

Genitourinary System: Spasm of vesical sphincters, ureteral spasm, and urinary retention.

Hematologic: Agranulocytosis, hemolytic anemia, iron deficiency anemia, prolonged bleeding time, thrombocytopenia.

Hypersensitivity: Allergic reactions.

Musculoskeletal: Skeletal muscle flaccidity.

Respiratory Depression: Acute airway obstruction, apnea, dose-related respiratory depression (see OVERDOSAGE), shortness of breath.

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

Skin: Cold and clammy skin, diaphoresis, pruritus, rash.

DRUG ABUSE AND DEPENDENCE

Misuse, Abuse and Diversion of Opioids

Zamiset[®] contains hydrocodone, an opioid agonist, and is a Schedule II controlled substance. Zamiset[®], 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 coagulation defects 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.

Treatment

A single or multiple drug 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. Oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed as indicated. Assisted or controlled ventilation should also be considered.

For hydrocodone overdose, primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including hydrocodone. Since the duration of action of hydrocodone may exceed that of the antagonist, the patient should be kept under continued 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.

Gastric decontamination with activated charcoal should be administered just prior to N-acetylcysteine (NAC) to decrease systemic absorption if acetaminophen ingestion is known or suspected to have occurred within a few hours of presentation. Serum acetaminophen levels should be obtained immediately if the patient presents 4 hours or more after ingestion to assess potential risk of hepatotoxicity; acetaminophen levels drawn less than 4 hours post-ingestion may be misleading. To obtain the best possible outcome, NAC should be administered as soon as possible where impending or evolving liver injury is suspected. Intravenous NAC may be administered when circumstances preclude oral administration.

Vigorous supportive therapy is required in severe intoxication. Procedures to limit the continuing absorption of the drug must be readily performed since the hepatic injury is dose dependent and occurs early in the course of intoxication.

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 tablespoonful (15 mL) every four to six hours as needed for pain. The total daily dosage should not exceed 6 tablespoonfuls.

The usual dosages for children are given by the table below, and are to be given every 4 to 6 hours as needed for pain. These dosages correspond to an average individual dose of 0.20 mL/kg of Zamicet[®] (providing 0.135 mg/kg of hydrocodone bitartrate and 4.38 mg/kg of acetaminophen). Dosing should be based on weight whenever possible.

BODY WEIGHT	APPROXIMATE AGE	DOSE every 4 to 6 hours	MAXIMUM TOTAL DAILY DOSE (6 doses per day)
12 to 15 kg (27 to 34 lbs)	2 to 3 years	2.8 mL (approx. ½ teaspoonful)	16.8 mL (approx. 3¼ teaspoonfuls)
16 to 22 kg (35 to 50 lbs)	4 to 6 years	3.75 mL (approx. ¾ teaspoonful)	22.5 mL (approx. 4½ teaspoonfuls)

23 to 31 kg (51 to 69 lbs)	7 to 9 years	5.6 mL (approx. 1 teaspoonful)	33.6 mL (approx. 6½ teaspoonfuls)
32 to 45 kg (70 to 100 lbs)	10 to 13 years	7.5 mL (approx. 1½ teaspoonfuls)	45 mL (approx. 9 teaspoonfuls)
46 kg and up (101 lbs and up)	14 years to adult	11.25 mL (approx. 2¼ teaspoonfuls)	67.5 mL (approx. 13½ teaspoonfuls)
—	adult	15 mL (1 Tablespoonful)	90 mL (6 Tablespoonfuls)

The total daily dosage for children should not exceed 6 doses per day. It is of utmost importance that the dose of Zamiset® be administered accurately. A household teaspoon or tablespoon is not an adequate measuring device, especially when one-half or three-fourths of a teaspoonful is to be measured. Given the inexactitude of the household spoon measure and the possibility of using a tablespoon instead of a teaspoon, which could lead to overdosage, it is strongly recommended that caregivers obtain and use a calibrated measuring device. Health care providers should recommend a dropper that can measure and deliver the prescribed dose accurately, and instruct caregivers to use extreme caution in measuring the dosage.

HOW SUPPLIED

Zamiset® is a yellow-colored, fruit flavored liquid containing 10 mg hydrocodone bitartrate and 325 mg acetaminophen per 15 mL, with 6.7% alcohol. It is supplied in the following oral dosage forms:

Bottles of 4 fl oz (118 mL) – NDC 0486-0771-04

Bottles of 16 fl oz (473 mL) – NDC 0486-0771-16

Unit dose cups of 7.5 mL packaged in trays of 10 – NDC 0486-4771-07

Unit dose cups of 15 mL packaged in trays of 10 – NDC 0486-4771-15

Storage

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]

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

A Schedule CII Narcotic

Manufactured for:

Beach

Div. of Beach Products, Inc., Tampa, FL 33611

R02/15

1077100B

Patient Information Leaflet

Zamiset® CII
(hydrocodone bitartrate and acetaminophen oral solution)
10 mg/325 mg per 15 mL

Rx ONLY

Summary

Zamiset® (hydrocodone bitartrate and acetaminophen oral solution) is used to relieve moderate to

moderately severe pain. You should not take this medicine if you are allergic to hydrocodone or acetaminophen. The most common side effects of this medicine are abdominal pain, dizziness, drowsiness, light-headedness, nausea, shortness of breath, unusual tiredness, and vomiting. Take this medicine as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered.

Uses

Zamiset[®] is an analgesic used to relieve moderate to moderately severe pain. Zamiset[®] is a combination product containing hydrocodone (hye-droe-KO-done) bitartrate and acetaminophen (a-seat-a-MIN-oh-fen). Hydrocodone is a narcotic pain reliever and a cough suppressant. Acetaminophen is a non-narcotic pain reliever and fever reducer. A narcotic analgesic and acetaminophen used together may provide better pain relief than either product used alone. If you have any questions, please call your doctor or pharmacist.

General Cautions

- Do not take this drug if you have allergies or unusual reactions to narcotic pain relievers or acetaminophen because it is likely that you may also be allergic to Zamiset[®].
- This product may inhibit your mental and physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. Such tasks should be avoided while you are taking this product.
- This medicine may not be right for you. Check with your doctor or pharmacist, if you:
 - are pregnant.
 - are nursing.
 - are taking other medications: narcotic pain relievers; allergy medicines; antidepressant medicines; acetaminophen-containing medicines or other medicines that cause central nervous system depression, including alcohol.
 - have other medical problems: a history of drug or alcohol abuse; recent head injury; emphysema, asthma, or other chronic lung disease; liver disease; kidney disease; underactive thyroid, Addison's disease, enlarged prostate or difficulty urinating.

Proper Use

Take this medicine as directed by your doctor. Do not share it with anyone else. This medicine can cause drug dependence and has the potential for abuse. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. If you think that this medicine is not working properly after taking it for some time, do not increase the dose. Check with your doctor or pharmacist.

Dosing

The dose of this medication will be different for different patients. Follow the directions provided by your doctor. The following information includes only the average dose of this medication. *If your dose is different, do not change doses unless your doctor tells you to do so.*

BODY WEIGHT	APPROXIMATE AGE	DOSE every 4 to 6 hours	MAXIMUM TOTAL DAILY DOSE (6 doses per day)
12 to 15 kg (27 to 34 lbs)	2 to 3 years	2.8 mL (approx. ½ teaspoonful)	16.8 mL (approx. 3¼ teaspoonfuls)
16 to 22 kg (35 to 50 lbs)	4 to 6 years	3.75 mL (approx. ¾ teaspoonful)	22.5 mL (approx. 4½ teaspoonfuls)
23 to 31 kg (51 to 69 lbs)	7 to 9 years	5.6 mL (approx. 1 teaspoonful)	33.6 mL (approx. 6½ teaspoonfuls)

32 to 45 kg (70 to 100 lbs)	10 to 13 years	7.5 mL (approx. 1½ teaspoonfuls)	45 mL (approx. 9 teaspoonfuls)
46 kg and up (101 lbs and up)	14 years to adult	11.25 mL (approx. 2¼ teaspoonfuls)	67.5 mL (approx. 13½ teaspoonfuls)
—	adult	15 mL (1 Tablespoonful)	90 mL (6 Tablespoonfuls)

It is very important that Zamicet[®] be dosed accurately. A household teaspoon or tablespoon is not an accurate measuring device, especially when one-half or three-fourths of a teaspoonful is to be measured.

Since a household teaspoon is not accurate and can be mixed-up with a tablespoon (which can cause overdosage), it is strongly recommended that you obtain and use a proper measuring device. Ask your doctor or pharmacist for help to find a dropper that can measure the needed dose properly and ask for help if you do not understand how to use the dropper.

Missed Dose

- To avoid a possible overdose, it is important that you do not take more than a single dosage at one time, or that you don't take doses at intervals less than 4 hours apart.
- If you miss taking a dose of Zamicet[®], take it as soon as you remember. However, make sure to wait at least 4 hours before taking your next dose.
- If you missed taking a dose, and it is almost time for your next dose, skip the missed dose and take your medicine as scheduled.
- Do not double the prescribed dose.

Possible Side Effects

Side effects you may experience include abdominal pain, constipation, difficulty urinating, dizziness, drowsiness, fear, fuzzy thinking, general feeling of discomfort or illness, light-headedness, mood changes, nausea, nervousness, rash, shortness of breath, slower reactions, unusual tiredness, and vomiting.

Call your doctor if these effects continue or are bothersome.

Side effects not listed above may sometimes occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Storage

- Keep out of reach of children.
- Store at room temperature (protect from heat, do not refrigerate).
- Keep in original labeled bottle.
- Discard medicines that are old or no longer needed.
- Even a single overdose of this medicine may be a life-threatening situation. If you suspect that you or someone else may have taken more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately. This medicine was prescribed for your particular condition. Do not use it for another condition or give the drug to others.
- This leaflet provides a summary of information about Zamicet[®]. If you have any questions or concerns, or want more information about Zamicet[®], contact your doctor or pharmacist. Your pharmacist also has a longer leaflet about Zamicet[®] that is written for health professionals that you can ask to read.

Manufactured for:

Beach

Div. of Beach Products, Inc., Tampa, FL 33611

R02/15
1077100B

PRINCIPAL DISPLAY PANEL - 15 mL Cup Label

Delivers 15 mL
NDC 0486-4771-15

Zamicet®
*(Hydrocodone Bitartrate and
Acetaminophen Oral Solution)*
CII

10 mg/325 mg per 15 mL

Alcohol 6.7%

FOR INSTITUTIONAL USE ONLY

See Package Insert for Dosage

Rx ONLY

Mfg. for: Beach Pharmaceuticals
Tampa, FL 33611

A47711500B



PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 0486-0771-04

Zamicet®
(Hydrocodone Bitartrate and Acetaminophen Oral Solution)
CII

10 mg/325 mg per 15 mL

Contains: **Per**
 15 mL
 Hydrocodone 10 mg
 Bitartrate
 Acetaminophen 325 mg
 Alcohol 6.7%

Rx ONLY

4 fl oz (118 mL)

Beach

Beach Pharmaceuticals, A Division of Beach Products, Inc., Tampa, FL

NDC 0486-0771-04

Zamicet®
 (Hydrocodone Bitartrate and Acetaminophen Oral Solution) **CII**

10 mg/325 mg per 15 mL

Contains: **Per**
 15 mL
 Hydrocodone 10 mg
 Bitartrate 325 mg
 Acetaminophen.....
 Alcohol 6.7%

Rx ONLY
4 fl oz (118 mL)

Beach
 Beach Pharmaceuticals, A Division of Beach Products, Inc., Tampa, FL

PHARMACIST: Dispense the important patient information leaflet with the drug product. The leaflet is included with the package insert.

Dispense in a tight, light-resistant container with a child-resistant closure. Store at 20° to 25°C (68° to 77°F) (See USP Controlled Room Temperature).

WARNING: Keep this and all medications out of the reach of children.

USUAL DOSAGE: See Package Insert for Complete Dosage Recommendations.

LOT:
EXP:

0486-0771-04

Mfg. for: Beach Pharmaceuticals
 Tampa, FL 33611

L07710400B R01/15

ZAMICET

hydrocodone bitartrate and acetaminophen solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0486-4771
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	5 mg in 7.5 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	163 mg in 7.5 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0486-4771-07	4 in 1 CASE		
1		10 in 1 TRAY		
1		7.5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0486-4771-15	4 in 1 CASE		
2		10 in 1 TRAY		
2		15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040834	03/18/2015	

ZAMICET

hydrocodone bitartrate and acetaminophen solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0486-0771
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 in 15 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7H9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	YELLOW	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0486-0771-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0486-0771-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040834	03/18/2015	

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	MANUFACTURE(0486-0771, 0486-4771)

Revised: 3/2015

Pharmaceutical Associates, Inc.