Hydrocodone Bitartrate and Acetaminophen Oral Solution is supplied in liquid form for oral administration.

WASNGS
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 anaphylactic reactions requiring emergency medical attention. Instruct patients to discontinue Hydrocodone Bitartrate and Acetaminophen Oral Solution immediately and seek medical care if they experience these symptoms as they appear.

Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 be more severe and/or prolonged in patients with head injuries.

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

Nausea, Abuse, and Diversion of Opioids:
Hydrocodone Bitartrate and Acetaminophen Oral Solution 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.

Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 Oral Solution in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion (see PRECAUTIONS, ABUSE, AND DIVERSION).

PRECAUTIONS
General
Special Risk Patients
As with any narcotic analgesic agent, Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 Oral Solution is used postoperatively and in patients with pulmonary disease.

Information for Patients/Caregivers
• Do not take Hydrocodone Bitartrate and Acetaminophen Oral Solution if you are allergic to any of its ingredients.
• If you develop signs of allergy such as a rash or difficulty breathing, stop taking Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 Hydrocodone Bitartrate and Acetaminophen Oral Solution may exhibit an additive CNS depression. When concomitant therapy is contemplated, the dose of one or both agents should be reduced.

The use of MAO inhibitors or tricyclic antidepressants with hydrocodone presents a risk of a potentially life-threatening drug interaction. Administration of hydrocodone should be avoided when concomitantly using these agents. If the use of hydrocodone is contemplated in a patient taking a MAO inhibitor, the dose of hydrocodone should be reduced and the patient observed closely.

Pregnancy
Teratogenic Effects:
There have been adequate and well-controlled studies in pregnant women. Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 increased crying, tremors, hyperactive reflexes, increased respiratory rate, increased tone, sneezing, yawning, and vomiting. These signs appear usually 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 antagonists 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 antagonists should be avoided during labor if delivery of a premature infant is anticipated. If the mother has received narcotic antagonists during labor, neonatal infants should be observed closely for signs of respiratory depression. Resuscitation may be required (see OVERDOSAGE). The effect of hydrocodone, if any, on the neonate, labor, delivery, and functional maturation of the child is unknown.

Nursing Mothers
Acetaminophen is excrated 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 excrated 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 Oral Solution 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 or 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, 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
To report SUSPECTED ADVERSE REACTIONS, contact GW Laboratories, Inc. at 1-800-922-1018 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Potential effects of high dosage are also listed in the OVERDOSAGE section.
Cardiovascular: 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, urethral spasm, and urinary retention.

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

Hypersensitivity: Musculoskeletal: Skeletal muscle flaccidity.

Respiratory Depression: Acute airway obstruction, apnea, dose-related respiratory depression (see OVERDOSES), 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
Hydrocodone Bitartrate and Acetaminophen Oral Solution contains hydrocodone, an opioid agonist, and is a Schedule II controlled substance. Hydrocodone Bitartrate and Acetaminophen Oral Solution, 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, use despite harm, use despite desire to cut down or control drug use, and failure to fulfill major role obligations. This information should not be construed as comprehensive guidance for all possible scenarios. 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 refusal to provide prior medical records or contact information for treatment that is entirely contrived by the patient(s). “Doctor shopping” to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction.

Abuse and dependence are separate and distinct from physical dependence and tolerance. Physical dependence usually accompanies clinical addiction, but it can also 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 Oral Solution, like other opioids, may be diverted non-medically use. Record-keeping of prescribing information, including quantity, frequency, and renewal requests is strongly advised. Proper assessment of the patient, proper prescribing practices, periodic revulsion of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

OVERDOSES

Following an acute overdose, 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 overdose, apnea, circulatory collapse, cardiac arrest and death may occur.

Acetaminophen: In acetaminophen overdose: 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 should include support of cardiopulmonary function and measures to reduce drug absorption. Oxygen, intravenous fluids, vasopressors, and other supportive measures should be directed as indicated. Assisted or controlled ventilation should also be considered. For hydrocodone overdose, primary attention should be given to the establishment 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 and highly effective antagonist in respiratory depression which may result from overdose 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.

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 Hydrocodone Bitartrate and Acetaminophen Oral Solution.

Summary
Hydrocodone Bitartrate and Acetaminophen Oral Solution is used to relieve mild to moderate pain. You should take Hydrocodone Bitartrate and Acetaminophen Oral Solution if you are allergic to hydrocodone or acetaminophen. The most common side effects of Hydrocodone Bitartrate and Acetaminophen Oral Solution are abdominal pain, dizziness, drowsiness, light-headedness, nausea, shortness of breath, unusual dizziness, 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.

Users
Hydrocodone Bitartrate and Acetaminophen Oral Solution is an analgesic that is moderately to moderately severe pain. Hydrocodone Bitartrate and Acetaminophen Oral Solution is a combination product containing hydrocodone (a-keto-ko-dine) bitartrate and acetaminophen (a-sea-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 consult your doctor or pharmacist.

Possible Side Effects
Side effects you may experience include abdominal pain, constipation, diarrhea, dizziness, drowsiness, drowsiness, headache, dizziness, mood changes, nausea, vomiting, nervousness, rash, shortness of breath, slurred speech, unusual tiredness, and vomiting.

Call your doctor if these effects continue or are bothersome.

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

A Schedule CII Narcotic
Manufactured by: S&W Laboratories, Inc.
111 Coolidge Street
South Plainfield, NJ 07080
Rev. 08/14 8-0704GW2

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

Patient Information Leaflet
Hydrocodone Bitartrate and Acetaminophen Oral Solution

7.5 mg/325 mg per 15 mL

Only

• 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.

• The medication 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; encephalitis, 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 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.

Dosage
The dose of this medicine will be different for different patients. Follow the directions provided by your doctor. The following information includes only the average doses 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
2 to 3 years
3/4 teaspoonful
27.5 mL
7.5 mg and acetaminophen 325 mg per 15 mL

16 to 22 kg
3 to 5 years
1 teaspoonful
3.75 mL
5 mg

23 to 31 kg
5 to 9 years
2 teaspoonfuls
7.5 mL
10 mg

32 to 50 kg
10 to 13 years
2 1/2 teaspoonfuls
12.5 mL
20 mg

46 kg and up
14 years to adult
1 tablespoonful
15 mL
45 mg

The total daily dosage for children should not exceed 6 doses per day.

It is of utmost importance that the dose of Hydrocodone Bitartrate and Acetaminophen Oral Solution 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 teaspoon instead of a teaspoon, which could lead to overdose, it is strongly recommended that caregivers obtain and use a calibrated measuring device. Health care providers should recommend a doctor should be able to measure and deliver the prescribed dose accurately, and instruct caregivers to use extreme caution in measuring the dosage.

How Supplied
Hydrocodone Bitartrate and Acetaminophen Oral Solution, is a sterile,odored, tropical fruit punch flavored liquid containing hydrocodone bitartrate (WARNING: may be habit-forming) 7.5 mg and acetaminophen 325 mg per 15 mL with 7% alcohol. It is supplied in containers of one pint (473 mL).

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

Pharmacist: Dispense in a tight, light-resistant container with a child-resistant closer.

A Schedule CII Narcotic
Manufactured by: S&W Laboratories, Inc.
111 Coolidge Street
South Plainfield, NJ 07080
Rev. 08/14 8-0704GW2