

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

^N**HYCODAN**[®]
(hydrocodone bitartrate)
TABLETS USP, 5mg
SYRUP, 5 mg/5 mL

Antitussive

Bristol-Myers Squibb Canada
Montreal, Canada
H4S-0A4

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^N **HYCODAN* TABLETS**

(hydrocodone bitartrate)

^N **HYCODAN* SYRUP**

(hydrocodone bitartrate)

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Nonmedicinal Ingredients
Oral	Tablets, 5mg	Corn starch, lactose, pregelatinized tapioca starch, stearic acid, talc and zinc stearate Sodium- and tartrazine- free
	Syrup, 5 mg/5 mL	Artificial cherry flavour, caramel syrup, FD&C RED No. 2, hydrochloric acid, methylparaben, propylparaben, purified water, sorbitol solution 70% and sucrose Alcohol-, lactose-, sodium-, sulphite- and tartrazine-free

INDICATIONS AND CLINICAL USE

Adults

HYCODAN (hydrocodone bitartrate) is indicated for the control of exhausting, non-productive cough.

Geriatrics (> 65 years of age)

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, concomitant disease or other drug therapy (see [ACTION AND CLINICAL PHARMACOLOGY, Special Populations and Conditions, Geriatrics](#)).

Pediatrics (< 18 years of age)

The use of hydrocodone is contraindicated in patients below the age of 6 years.

CONTRAINDICATIONS

- Patients who are hypersensitive to the active substance hydrocodone bitartrate or other opioid analgesics or to any ingredient in the formulation. Patients known to be hypersensitive to

other opioids may exhibit cross sensitivity to hydrocodone. For a complete listing, see the [DOSAGE FORMS, COMPOSITION AND PACKAGING](#) section of the Product Monograph.

- In patients with known or suspected mechanical gastrointestinal obstruction (e.g., bowel obstruction or strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type).
- Patients with acute or severe bronchial asthma, chronic obstructive airway, or status asthmaticus.
- Patients with acute respiratory depression, elevated carbon dioxide levels in the blood and cor pulmonale.
- Patients with acute alcoholism, delirium tremens, and convulsive disorders.
- Patients with severe CNS depression, increased cerebrospinal or intracranial pressure, and head injury.
- Patients taking monoamine oxidase (MAO) inhibitors (or within 14 days of such therapy).
- Women who are pregnant or during labour and delivery.
- Patients under the age of 6

WARNINGS AND PRECAUTIONS

SERIOUS WARNINGS AND PRECAUTIONS

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death (see WARNINGS AND PRECAUTIONS). Avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol.

General

Before prescribing medication to suppress or modify cough, it is important to ascertain that the underlying cause of the cough is identified, that modification of the cough does not increase the risk of clinical or physiological complications, and that appropriate therapy for the primary disease is provided.

Accidental ingestion, especially by children can result in a fatal overdose of hydrocodone bitartrate (see [DOSAGE AND ADMINISTRATION](#), [Disposal](#), for instructions on proper disposal).

Patients should be cautioned not to consume alcohol while taking HYCODAN (hydrocodone bitartrate) as it may increase the chance of experiencing serious adverse events, including death.

Abuse and Misuse

Like all opioids, **HYCODAN** is a potential drug of abuse and misuse, which can lead to overdose and death. Therefore, **HYCODAN** should be prescribed and handled with caution.

Opioids, such as **HYCODAN**, should be used with particular care in patients with a history of alcohol and illicit/prescription drug abuse.

Carcinogenesis and Mutagenesis

Carcinogenicity and mutagenicity studies have not been conducted with **HYCODAN**

Cardiovascular

Hydrocodone bitartrate administration may result in hypertension, hypotension, palpitations and dizziness.

Dependence/Tolerance

As with other opioids, tolerance and physical dependence may develop upon repeated administration of **HYCODAN** and there is a potential for development of psychological dependence.

Physical dependence and tolerance reflect the neuroadaptation of the opioid receptors to chronic exposure to an opioid, and are separate and distinct from abuse and addiction. Tolerance, as well as physical dependence, may develop upon repeated administration of opioids, and are not by themselves evidence of an addictive disorder or abuse.

Treatment of withdrawal is usually managed by providing sufficient quantities of an opioid to suppress severe withdrawal symptoms and then gradually reducing the dose of opioid over a period of several days.

Gastrointestinal Effects

Hydrocodone bitartrate and other morphine-like opioids have been shown to decrease bowel motility. Hydrocodone bitartrate may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Patients with chronic constipation should be given the drug only after weighing the potential therapeutic benefit against the hazards involved.

Neonatal Opioid Withdrawal Syndrome (NOWS)

Use of **HYCODAN** is contraindicated in pregnant women (see [CONTRAINDICATIONS](#)).

Prolonged maternal use of opioids during pregnancy can result in withdrawal signs in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening.

Neonatal opioid withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea, increased respiratory rate, increased stool,

sneezing, yawning, fever and failure to gain weight. The onset, duration, and severity of neonatal opioid withdrawal syndrome vary based on the specific opioid used, duration of use, timing and amount of last maternal use, and rate of elimination of the drug by the newborn.

The intensity of the syndrome does not always correlate with the duration of maternal opioids use or dose. There is no consensus on the best method of managing withdrawal. Chlorpromazine 0.7 to 1.0 mg/kg q6h, phenobarbital 2 mg/kg q6h, and paregoric 2 to 4 drops/kg q4h, have been used to treat withdrawal symptoms in infants. The duration of therapy is 4 to 28 days, with the dosages decreased as tolerated.

Neurologic

Interactions with Central Nervous System Depressants (including benzodiazepines and alcohol):

Concomitant use of opioids, including HYCODAN, with benzodiazepines, or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Because of these risks, avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol (see **CONTRAINDICATIONS and DRUG INTERACTIONS**).

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. Because of similar pharmacologic properties, it is reasonable to expect similar risk with concomitant use of opioid cough medications and benzodiazepines, other CNS depressants, or alcohol.

Advise both patients and caregivers about the risks of respiratory depression and sedation if HYCODAN is used with benzodiazepines, alcohol, or other CNS depressants.

Head Injury: The respiratory depressant effects of Hydrocodone bitartrate, and the capacity to elevate cerebrospinal fluid pressure, may be greatly increased in the presence of an already elevated intracranial pressure produced by trauma. Also, Hydrocodone bitartrate may produce confusion, miosis, vomiting and other side effects which obscure the clinical course of patients with head injury. In such patients, Hydrocodone bitartrate must be used with extreme caution and only if it is judged essential (see [CONTRAINDICATIONS](#)).

Psychomotor Impairment

HYCODAN may impair the mental and/or physical abilities needed for certain potentially hazardous activities such as driving a car or operating machinery. Patients should be cautioned accordingly. Patients should also be cautioned about the combined effects of Hydrocodone bitartrate with other CNS depressants, including other opioids, phenothiazine, sedative/hypnotics and alcohol.

Respiratory

Hydrocodone bitartrate, including HYCODAN is not recommended for use in any patient in whom respiratory function might be compromised including neuromuscular disorders, severe cardiac or respiratory conditions, lung infections, multiple trauma or extensive surgical procedures.

Life-threatening respiratory depression is more likely to occur in the elderly, cachectic, or debilitated patients because they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients.

In patients with asthma or pulmonary emphysema, indiscriminate use may precipitate respiratory insufficiency resulting from increased viscosity of bronchial secretions and suppression of the cough reflex.

The use of hydrocodone is contraindicated in patients below the age of 6 years. In young children, the respiratory centre is especially susceptible to the depressant action of narcotic cough suppressants. The use of hydrocodone bitartrate in children less than 6 years of age has been associated with fatal respiratory depression. A 5 year old child treated for cough died after a few hours of exposure to hydrocodone bitartrate; the child was a CYP2D6 poor metabolizer and was concomitantly exposed to clarithromycin, a CYP3A4 inhibitor and valproic acid, a broad-spectrum inhibitor of the uridine diphosphate glucuronosyltransferases (UGTs), resulting in blood hydrocodone levels associated with fatality. Such a scenario of hydrocodone overdose can be equally plausible in CYP2D6 intermediate, extensive, and ultrarapid metabolizers, especially in the presence of other drug interactions and physical vulnerabilities for children up to 18 years of age and adults. Exercise caution when administering HYCODAN in children ages 6 and up because of the potential for respiratory depression. If respiratory depression occurs, discontinue and use naloxone hydrochloride when indicated to antagonize the effect and other supportive measures as necessary. The benefit to risk ratio should be carefully considered, especially in children with respiratory embarrassment (e.g. croup). Estimation of dosage relative to the child's age and weight is of great importance.

Use in Patients with Chronic Pulmonary Disease: Monitor patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression for respiratory depression, particularly when initiating therapy and titrating with HYCODAN, as in these patients, even usual therapeutic doses of HYCODAN may decrease respiratory drive to the point of apnea. The use of HYCODAN is contraindicated in patients with acute or severe bronchial asthma, chronic obstructive airway, or status asthmaticus (see [CONTRAINDICATIONS](#)).

Special Populations

Special Risk Groups: Hydrocodone bitartrate should be administered with caution to patients with a history of alcohol and drug abuse and in a reduced dosage to debilitated patients, and in patients with severely impaired pulmonary function, Addison's disease, hypothyroidism, myxedema, toxic psychosis, prostatic hypertrophy or urethral stricture.

Use with caution in sedated or debilitated patients, in patients who have undergone thoracotomies or laparotomies, since suppression of the cough reflex may lead to retention of secretions postoperatively in these patients.

Pregnant Women: Studies in humans have not been conducted. HYCODAN crosses the placental barrier. HYCODAN is contraindicated in pregnant patients (see [CONTRAINDICATIONS](#)).

Prolonged maternal use of opioids during pregnancy can result in withdrawal signs in the neonate. Neonatal Opioid Withdrawal Syndrome (NOWS), unlike opioid withdrawal syndrome in adults, may be life-threatening (see [WARNINGS AND PRECAUTIONS, Neonatal Opioid Withdrawal Syndrome](#), **ADVERSE REACTIONS, Post-marketing Experience**.)

Labour, Delivery and Nursing Women: Respiratory depression can occur in the infant if opioids are administered during labour. Naloxone, a drug that counters the effects of opiates, should be readily available.

Labour and Delivery

Since opioids can cross the placental barrier and are excreted in breast milk, HYCODAN should not be used during labour and delivery (see [CONTRAINDICATIONS](#)).

Nursing Women:

Since opioids can cross the placental barrier and are excreted in breast milk, HYCODAN should not be used in nursing women unless, in the judgement of the physician, the potential benefits outweigh the risks.

Pediatrics (< 18 years of age): In young children the respiratory centre is especially susceptible to the depressant action of narcotic cough suppressants. Benefit to risk ratio should be carefully considered, especially in children with respiratory embarrassment, e.g., croup. Estimation of dosage relative to the child's age and weight is of great importance. The use of hydrocodone is contraindicated in patients below the age of 6 years due to increased safety concerns (i.e. respiratory depression) regardless of clinical setting (see **CONTRAINDICATIONS**).

Geriatrics (> 65 years of age): In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range and titrate slowly, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy (see [DOSAGE AND ADMINISTRATION](#)).

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Adverse Drug Reactions:

Cardiovascular: Hypertension, postural hypotension and palpitations.

Central nervous: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes and blurred vision.

Gastrointestinal: Nausea and vomiting occur more frequently in ambulatory than in recumbent patients. Constipation may also occur.

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

Respiratory: Hydrocodone produces dose-related respiratory depression by acting directly on brain stem respiratory centers.

Other

Drug Abuse and Dependence

Patients physically dependent on opioids will develop an abstinence syndrome upon abrupt discontinuation of the opioid or following the administration of a narcotic antagonist. The character and severity of the withdrawal symptoms are related to the degree of physical dependence. Manifestations of opioid withdrawal are similar to but milder than that of morphine and include lacrimation, rhinorrhea, yawning, sweating, restlessness, dilated pupils, anorexia, gooseflesh, irritability and tremor. In more severe forms, nausea, vomiting, intestinal spasm and diarrhea, increased heart rate and blood pressure, chills, and pains in bones and muscles of the back and extremities may occur. Peak effects will usually be apparent at 48 to 72 hours.

DRUG INTERACTIONS

Interaction with Benzodiazepines and Other Central Nervous System (CNS) Depressants (including alcohol): Due to additive pharmacologic effect, the concomitant use of benzodiazepines or other CNS depressants (e.g. other opioids, sedatives/hypnotics, antidepressants, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, phenothiazines, neuroleptics, antihistamines, antiemetics, and alcohol) and beta-blockers, increases the risk of respiratory depression, profound sedation, coma, and death and should be avoided (see **WARNINGS AND PRECAUTIONS, Neurologic, Interactions with Central Nervous System Depressants (including benzodiazepines and alcohol) and Psychomotor Impairment**). HYCODAN should not be consumed with alcohol as it may increase the chance of experiencing dangerous side effects.

Drug-Lifestyle Interactions

The concomitant use of alcohol should be avoided (see [WARNINGS AND PRECAUTIONS, General](#)).

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

Adults:

One HYCODAN* TABLET or 5 mL (one teaspoonful) of HYCODAN SYRUP not less than 4 hours apart, after meals and at bedtime with food or a glass of milk, not to exceed six tablets or 30 mL (six teaspoonfuls) of syrup in a 24-hour period. Maximum single dose three tablets or 15 mL (three teaspoonfuls) of syrup.

Pediatrics:

The use of hydrocodone is contraindicated in patients below the age of 6 years due to increased safety concerns (i.e. respiratory depression) regardless of clinical setting. (See [CONTRAINDICATIONS](#), [WARNINGS AND PRECAUTIONS, Respiratory](#) and [Special Populations, Pediatrics](#))

Over 12 yrs: One HYCODAN TABLET or 5 mL (one teaspoonful) of HYCODAN SYRUP not less than 4 hours apart, after meals and at bedtime with food or a glass of milk, not to exceed 30 mL (six teaspoonfuls) in a 24-hour period. Maximum single dose two tablets or 10 mL (two teaspoonfuls) of syrup.

Age 6 to 12 yrs: One half of a HYCODAN* TABLET or 2.5 mL (1/2 teaspoonful) of HYCODAN* SYRUP not less than 4 hours apart, after meals and at bedtime with food or a glass of milk, not to exceed a total of three tablets or 15 mL (three teaspoonfuls) of syrup in a 24-hour period. Maximum single dose one tablet or 5 mL (1 teaspoonful) of syrup.

Geriatrics:

Respiratory depression has occurred in the elderly following administration of large initial doses of opioids to patients who were not opioid-tolerant or when opioids were co-administered with other agents that can depress respiration. HYCODAN should be initiated at a low dose and slowly titrated to effect (see [WARNINGS AND PRECAUTIONS](#)).

Disposal

HYCODAN should be kept in a safe place, out of the sight and reach of children before, during and after use. HYCODAN should not be used in front of children, since they may copy these actions.

HYCODAN should never be disposed of in household trash. Disposal via a pharmacy take back program is recommended. Unused or expired HYCODAN should be properly disposed of

as soon as it is no longer needed to prevent accidental exposure to others, including children or pets.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Symptoms:

Serious overdosage with hydrocodone may be 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.

Treatment:

Primary attention should be given to the re-establishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including hydrocodone. An appropriate dose of naloxone hydrochloride should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. 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. The instructions contained in the package insert should be carefully observed. Oxygen, intravenous fluids, vasopressors, and other supportive measures should be employed as indicated. Gastric emptying may be useful in removing unabsorbed drug. Activated charcoal may be of benefit.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

Clinical trials have proven hydrocodone bitartrate to be an effective antitussive agent which is pharmacologically two to eight times as potent as codeine. At equieffective doses, its sedative action is greater than that of codeine. The precise mechanisms of action of hydrocodone and other opiates are not known; however, hydrocodone is believed to act by directly depressing the cough center. In excessive doses, hydrocodone like other opium derivatives, can depress respiration. The effects of therapeutic doses of hydrocodone on the cardiovascular system are insignificant. The constipating effects of hydrocodone are much weaker than those of morphine and no stronger than those of codeine. Hydrocodone can produce miosis, euphoria, physical and psychological dependence.

Pharmacokinetics

At therapeutic antitussive doses, it does exert analgesic effects. Following a 10 mg oral dose of hydrocodone administered to five male human subjects, the mean peak serum 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 0-demethylation, N-demethylation and 6-keto reduction to the corresponding 6- α - and 6- β -hydroxymetabolites.

Special Populations and Conditions

Pediatrics: See [WARNINGS and PRECAUTIONS](#)

Geriatrics: See [WARNINGS and PRECAUTIONS](#)

STORAGE AND STABILITY

Patients should be instructed to store HYCODAN, as for any medication, well out of the reach of children. Keep tightly closed. Store at 15° to 30 °C. Dispense HYCODAN SYRUP in a tight, light-resistant container.

SPECIAL HANDLING INSTRUCTIONS

Not applicable.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Composition:

HYCODAN TABLETS

Each white, biconvex and bisected tablet contains: hydrocodone bitartrate 5 mg. Nonmedicinal ingredients: cornstarch, lactose, pregelatinized tapioca starch, stearic acid, talc and zinc stearate. Sodium- and tartrazine-free.

HYCODAN SYRUP

Each 5 mL of red, wild cherry-flavored syrup contains: hydrocodone bitartrate 5 mg. Nonmedicinal ingredients: artificial cherry flavour, caramel syrup, FD&C RED No. 2, hydrochloric acid, methylparaben, propylparaben, purified water, sorbitol solution 70% and sucrose. Alcohol-, lactose-, sodium-, sulfite- and tartrazine-free.

Packaging:

HYCODAN TABLETS are supplied in bottles of 100 tablets.

HYCODAN SYRUP is supplied in bottles of 100 mL and 500 mL.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name:

Hydrocodone bitartrate

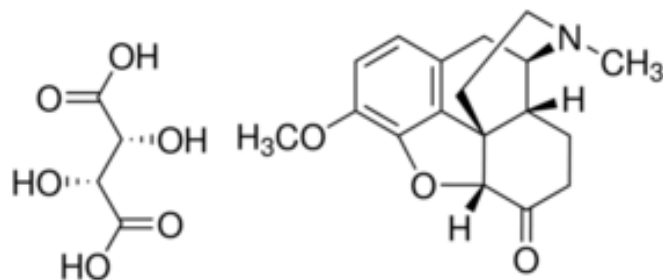
Chemical name:

Hydrocodone is 7,8-dihydrocodeinone, a derivative of codeine.

Molecular formula and molecular mass:

$C_{18}H_{21}NO_3$ and 299.36

Structural formula:



Physicochemical Properties:

Fine white or slightly yellow-white powder. Odorless. Solubility: soluble in water and 95% ethanol. Insoluble in chloroform.

PART III: PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

^NHYCODAN[®]

(hydrocodone bitartrate)

Tablets and Syrup

Read this carefully before you start taking **HYCODAN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **HYCODAN**.

What is HYCODAN used for?

HYCODAN is used for the temporary relief of cough associated with:

- allergies, or
- the common cold

Serious Warnings and Precautions

Taking HYCODAN with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

How does HYCODAN work?

Hydrocodone bitartrate acts on the brain to suppress cough.

What are the ingredients in HYCODAN?

HYCODAN TABLETS

Each white, biconvex and bisected tablet contains:

Medicinal ingredients: hydrocodone bitartrate 5 mg

Non-medicinal ingredients: Corn starch, lactose, pregelatinized tapioca starch, stearic acid, talc and zinc stearate. Sodium- and tartrazine-free.

HYCODAN SYRUP

Each 5 mL of red, wild cherry-flavored syrup contains:

Medicinal ingredients: hydrocodone bitartrate 5 mg

Non-medicinal ingredients: Artificial cherry flavour, caramel syrup, FD&C RED No. 2, hydrochloric acid, methylparaben, propylparaben, purified water, sorbitol solution 70% and sucrose. Alcohol-, lactose-, sodium-, sulfite- and tartrazine-free.

HYCODAN comes in the following dosage forms:

5 mg tablets and 5mg/5mL syrup

Do not use HYCODAN if you:

- are allergic to hydrocodone bitartrate or to any of the other ingredients in HYCODAN
- have severe asthma, trouble breathing, or other breathing problems
- have bowel blockage or narrowing of the stomach or intestines
- have a head injury
- are at risk for having seizures
- suffer from alcoholism
- are taking or have taken within the past 2 weeks a Monoamine Oxidase inhibitor (MAOi) (such as phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline)
- are pregnant or planning to become pregnant or you are in labour
- are younger than 6 years of age

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take HYCODAN. Talk about any health conditions or problems you may have, including if you:

- have a history of illicit or prescription drug or alcohol abuse and consequent to these, temporary mental disorders
- have severe kidney disease
- have severe liver disease
- have low blood pressure
- have severe breathing problems
- have problems with your thyroid, adrenal or prostate gland
- have or had depression
- suffer from chronic or severe constipation

- have, or had in the past hallucinations or other severe mental problems
- are pregnant or planning to become pregnant
- are breastfeeding

Other warnings you should know about:

Accidentally taking HYCODAN can result in a fatal overdose. This is especially true if a child accidentally takes it.

As with all opioids, taking hydrocodone bitartrate may cause you to become dependent on it. Do not take more than the dose prescribed to you by your doctor.

If you took HYCODAN while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:

- **has changes in their breathing (such as weak, difficult or fast breathing)**
- **is unusually difficult to comfort**
- **has tremors (shakiness)**
- **has increased stools, sneezing, yawning, vomiting, or fever**

Seek immediate medical help for your baby.

Young children are at risk of the sedating effects of narcotic cough drugs. The use of hydrocodone in children has led to slow, shallow or weak breathing that has been fatal. **HYCODAN** should not be given to children who have difficulty breathing. **IMPORTANT:** calculate the child's dose using their age and weight.

Driving and using machines: Before you do tasks which may require special attention, you should wait until you know how you react to HYCODAN. HYCODAN can cause:

- drowsiness
- dizziness or
- lightheadedness

This can usually occur after you take your first dose and when your dose is increased.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with HYCODAN:

- Alcohol. This includes prescription and non-prescription medications that contain alcohol. **Do not** drink alcohol while you are taking HYCODAN. It can lead to:
 - drowsiness

- unusually slow or weak breathing
- serious side effects or
- a fatal overdose
- opioid analgesics (drugs used to treat pain)
- general anesthetics (drugs used during surgery)
- benzodiazepines (drugs used to help you sleep or that help reduce anxiety)
- antidepressants (for depression and mood disorders). **Do not** take HYCODAN with MAO inhibitors (MAOi) or if you have taken MAOi's in the last 14 days.
- drugs used to treat serious mental or emotional disorders (such as schizophrenia)
- antihistamines (drugs used to treat allergies)
- anti-emetics (drugs used to prevent vomiting)
- drugs used to treat muscle spasms and back pain
- some heart medication (such as beta blockers)

How to take HYCODAN:

Usual Dose:

Adult Dosage

One HYCODAN TABLET or 5 mL (one teaspoonful) of HYCODAN SYRUP not less than 4 hours apart, after meals and at bedtime with food or a glass of milk, not to exceed six tablets or 30 mL (six teaspoonfuls) of syrup in a 24-hour period. Maximum single dose three tablets or 15 mL (three teaspoonfuls) of syrup.

Children's Dosage

Under 6 years of age: Do not use hydrocodone in patients below the age of 6 years.

Over 12 yrs: One HYCODAN TABLET or 5 mL (one teaspoonful) of HYCODAN SYRUP not less than 4 hours apart, after meals and at bedtime with food or a glass of milk, not to exceed 30 mL (six teaspoonfuls) in a 24-hour period. Maximum single dose two tablets or 10 mL (two teaspoonfuls) of syrup.

Age 6 to 12 yrs: One half of a HYCODAN TABLET or 2.5 mL (1/2 teaspoonful) of HYCODAN SYRUP not less than 4 hours apart, after meals and at bedtime with food or a glass of milk, not to exceed a total of three tablets or 15 mL (three teaspoonfuls) of syrup in a 24-hour period. Maximum single dose one tablet or 5 mL (1 teaspoonful) of syrup.

Overdose:

If you think you have taken too much HYCODAN, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion
- extreme drowsiness

What are possible side effects from using HYCODAN?

These are not all the possible side effects you may feel when taking HYCODAN. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- drowsiness
- insomnia
- dizziness
- fainting
- nausea, vomiting, or a poor appetite
- dry mouth
- headache
- problems with vision
- weakness, uncoordinated muscle movement
- itching
- sweating
- constipation

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE Overdose: hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, cold and clammy skin.			√
Respiratory Depression: slow, shallow or weak breathing.			√
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
Bowel Blockage (impaction): abdominal pain, severe constipation, nausea			√
Fast, Slow or Irregular Heartbeat: heart palpitations.		√	
Low Blood Pressure: dizziness, fainting, light-headedness.	√		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

We encourage you to report serious or unexpected side effects to Health Canada. The information is used to check for new safety concerns about health products. As a consumer, your report contributes to the safe use of health products for everyone.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15° to 30 °C. Keep unused or expired HYCODAN in a secure place to prevent theft, misuse or accidental exposure to children and pets.

Keep HYCODAN out of sight and reach of children and pets.

Disposal:

HYCODAN should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.

If you want more information about HYCODAN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this consumer medication information by visiting the [Health Canada website](#); the manufacturer's website <http://www.bmscanada.ca>, or by calling 1-866-463-6267.

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Montréal, Canada H4S 0A4

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