



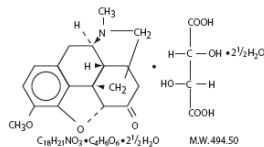
Levall® 5.0 Liquid (hydrocodone bitartrate, guaifenesin/phenylephrine hydrochloride)
Oral Solution
Rx Only

DESCRIPTION:

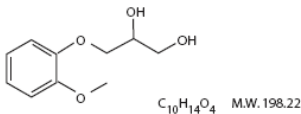
Each teaspoonful (5 mL) contains:

Hydrocodone Bitartrate	2.5 mg (Warning: May Be Habit Forming)
Guaifenesin	100 mg
Phenylephrine Hydrochloride	5 mg

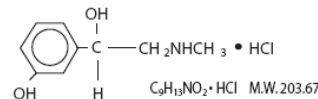
Inactive Ingredients: Glycerin, Maltitol, Propylene Glycol, Sorbitol, Sodium Saccharin, Grape Flavor, FD&C Red #40, FD&C Blue #1, Purified water.



Hydrocodone Bitartrate: (Morphinan-6-one,4,5-epoxy-3-methoxy-17-methyl-, (5*R*)-, [R-(*R**, *R**)]-2, 3-dihydroxybutanedioate (1:1), hydrate (2:5) is the bitartrate hemipentahydrate of hydrocodone, having the structural formula above:



Guaifenesin: 1,2-Propanediol, 3-(2-methoxyphenoxy)-, is a white to slightly gray, crystalline powder, having a bitter taste. It may have a slight characteristic odor. It is soluble in water, alcohol, chloroform, glycerin, and propylene glycol, having the structural formula above:



Phenylephrine Hydrochloride: (R)-3-Hydroxy- α -(methylamino) methyl Benzenemethanol hydrochloride which occurs as a white or practically white, odorless crystals, having a bitter taste. It is freely soluble in water and in alcohol, having the structural formula above:

CLINICAL PHARMACOLOGY:

Hydrocodone bitartrate is a narcotic antitussive providing cough relief for up to 6 hours. It acts in the medulla oblongata to elevate the cough threshold. Hydrocodone possesses narcotic analgesic properties; tolerance can develop and a potential for addiction exists. Hydrocodone is rapidly metabolized after ingestion, with trace amounts of unchanged drug in the blood and urine. Phenylephrine HCl is a sympathomimetic which acts predominantly on alpha receptors and has little action on beta receptors. They therefore function as oral nasal decongestants with minimal CNS stimulation. Guaifenesin has an expectorant action which increases the output of respiratory tract fluid by reducing adhesiveness and surface tension. Sinus and bronchial drainage is improved and dry, non-productive coughs become more productive and less frequent. Guaifenesin is an expectorant which increases respiratory tract fluid secretions and helps to loosen phlegm and bronchial secretions by reducing the viscosity of which increases respiratory tract fluid secretions and helps to loosen phlegm and bronchial secretions. By reducing the viscosity of secretions, guaifenesin increases the efficiency of the cough reflex and of ciliary action in removing accumulated secretions from the trachea and bronchi. Guaifenesin is readily absorbed from the gastrointestinal tract and is rapidly metabolized and excreted in the urine. Guaifenesin has a plasma half-life of one hour. The major urinary metabolite is β -(2-methoxyphenoxy) lactic acid. Phenylephrine hydrochloride, a sympathomimetic amine, acts directly on α -adrenergic receptors in the mucosa of the respiratory tract to produce vasoconstriction that increases peripheral resistance, resulting in an increase in both systolic and diastolic blood pressure. Accompanying the pressor response is a marked reflex bradycardia due to increased vagal activity. It produces vasoconstriction that lasts longer than that produced by ephedrine and epinephrine, and in therapeutic doses, produces little or no central nervous system (CNS) stimulation. Phenylephrine has reduced bioavailability from the gastrointestinal tract because of first pass metabolism by monoamine oxidase in the stomach and liver.

INDICATIONS AND USAGE:

For temporary relief of non-productive cough accompanying respiratory tract congestion associated with the common cold, influenza, sinusitis, and bronchitis.

CONTRAINDICATIONS:

Levall® 5.0 is contraindicated in infants and newborns, and in patients with a known hypersensitivity to any of the components. It is also contraindicated in patients with severe hypertension, severe coronary artery disease, hyperthyroidism, and in patients on MAO inhibitors therapy. Patient idiosyncrasy to adrenergic agents may be manifested by insomnia, dizziness, weakness, tremor, or arrhythmias.

DO NOT EXCEED RECOMMENDED DOSAGE.

WARNINGS:

Hydrocodone: May be habit-forming. Use with the same degree of caution as exercised with other narcotic containing medications since there is potential for drug dependence and abuse. Phenylephrine Hydrochloride: Sympathomimetic amines should be used with caution in patients with hypertension, ischemic heart disease, diabetes mellitus, increased intraocular pressure, hyperthyroidism, or prostatic hypertrophy. Sympathomimetics may produce central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension. Respiratory and CNS Effects: May cause respiratory depression or an exaggerated increase in cerebrospinal fluid pressure in the presence of other intracranial pathology.

PRECAUTIONS:

Drug Interactions: MAO inhibitors and beta adrenergic blockers increase the effects of sympathomimetics. Sympathomimetics may reduce the antihypertensive effects of methyl dopa, mecamylamine, reserpine, and veratrum alkaloids. Guaifenesin may produce an increase in urinary 5-hydroxy-indoleacetic acid and may therefore interfere with the interpretation of this test for the diagnosis of carcinoid syndrome. It may also falsely elevate the VMA test for catechols. Administration of this drug should be discontinued 48 hours prior to the collection of urine specimens for such tests. Before prescribing medication to suppress or modify cough, identify and provide therapy for the underlying cause of cough. Use with caution in patients with severe impairment of liver or kidney function, hypothyroidism, thyroid disease, Addison's disease, hypertension, heart disease, asthma, or increased intraocular pressure, diabetes mellitus, prostatic hypertrophy or urethral stricture. Narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions or head injuries.

Information for Patients: Patients receiving narcotic analgesics, alcohol, tranquilizers and other CNS depressants concomitantly with this product may exhibit CNS depression. Avoid alcohol while taking this product. Elderly or debilitated patients and those sensitive to narcotics should take this product with caution. Patients sensitive to antihistamines may experience moderate to severe drowsiness. Patients sensitive to sympathomimetic amines may note mild CNS stimulation. While taking this product, exercise care in driving or operating appliances, machinery, etc.

Drug Interactions: Antihistamines and narcotics such as hydrocodone may enhance the effects of tricyclic antidepressants, barbiturates, alcohol and other CNS depressants. MAO inhibitors prolong and intensify the anticholinergic effects of reserpine, veratrum alkaloids, methyl dopa and mecamylamine. The cough suppressant action of hydrocodone and other antitussives is additive.

Carcinogenesis, Mutagenesis, And Impairment Of Fertility: No adequate and well controlled studies have been conducted to determine whether the components of Levall® 5.0 have a potential for carcinogenesis, mutagenesis, or impairment of fertility.

PREGNANCY:

Pregnancy Category C: Animal reproduction studies have not been conducted with this product. It is also not known whether it can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This product should not be administered to pregnant women.

Nursing Mothers: Due to the possible passage of the ingredients into breast milk, this product should not be given to nursing mothers. Special Risk Patients: Use with caution in patients with hypertension or ischemic heart disease, and persons over 60 years.

ADVERSE REACTIONS:

Hydrocodone: Respiratory depression, sedation, dizziness, light-headedness, nausea, vomiting, constipation, skin rash, pruritus, euphoria and dysphoria. Milk central nervous system stimulation, especially in those patients who are hypersensitive to sympathomimetic drugs, may occur. Nervousness, excitability, restlessness, dizziness, weakness, and insomnia may also occur. Headache and drowsiness have also been reported. Large doses may cause light-headedness, nausea and/or vomiting. Sympathomimetic drugs have also been associated with certain untoward reactions including fear, anxiety, tenseness, restlessness, tremor, weakness, pallor, respiratory difficulty, dysuria, insomnia, hallucination, convulsion, CNS depression, arrhythmias and CARDIOVASCULAR COLLAPSE WITH HYPOTENSION.

DRUG ABUSE AND DEPENDENCE:

Hydrocodone may be habit-forming and can produce drug dependence of the morphine type, thereby having potential for abuse. Psychic dependence and tolerance may develop after repeated administration. Levall® 5.0, a Schedule III controlled substance, is subject to the Federal Controlled Substances Act.

OVERDOSAGE:

Overdose: No information is available as to specific results of an overdose of Levall® 5.0. The signs, symptoms and treatment described below are those of hydrocodone and phenylephrine HCl overdose. Symptoms: Should narcotic effects predominate, respiratory depression may occur, characterized by a decrease in respiratory rate and/or tidal volume. Cheyne-Stokes respiration and cyanosis, sleepiness, extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, bradycardia and hypotension may occur. Apnea, circulatory collapse, cardiac arrest and death may occur in severe cases. Central effects include restlessness, dizziness, tremor, hyperactivity reflexes, talkativeness, irritability and insomnia. Cardiovascular and renal effects include difficulty in urination, headache, flushing, palpitation, cardiac arrhythmias, hypertension with subsequent hypotension and circulatory collapse. Gastrointestinal effects include dry mouth, anorexia, nausea, vomiting, diarrhea, and abdominal cramps.

Treatment: The patient should be induced to vomit, even if emesis has occurred spontaneously. Pharmacologic vomiting by the administration of ipecac syrup is a preferred method, however, vomiting should not be induced in patients with impaired consciousness. Precautions against aspiration must be taken, especially in infants and children. Following emesis, any drug remaining in the stomach may be absorbed by activated charcoal administered as a slurry with water. Treatment of the signs and symptoms of overdose is symptomatic and supportive.

DOSAGE AND ADMINISTRATION:

Adults and children over 12 years: 10 mL (2 teaspoonfuls) every 4-6 hours; not to exceed 60 mL (12 teaspoonfuls) in 24 hours.

Children 6 to 12 years: 5 mL (1 teaspoonful) every 4-6 hours; not to exceed 30 mL (6 teaspoonfuls) in 24 hours.

Children 2 to 6 years: 2.5 mL (1/2 teaspoonful) every 4-6 hours; not to exceed 15 mL (3 teaspoonfuls) in 24 hours.

Children under 2 years: As directed by a physician.

HOW SUPPLIED:

Levall 5.0 is an alcohol-free, sugar-free oral solution with a grape flavor and aroma. Levall 5.0 is supplied in 16 fl. oz. (473 mL) bottles, NDC 14629-302-16.

STORAGE:

Store at 20°-25°C (68°-77°F); excursions permitted to 15°- 30°C (59°-86°F) See USP Controlled Room Temperature. **DISPENSE IN A TIGHT, LIGHT-RESISTANT CONTAINER AS DEFINED IN USP WITH A CHILDRESISTANT CLOSURE.**

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Rx Only

