

## Exall™-D Liquid

Rx only

Antitussive / Nasal Decongestant / Expectorant

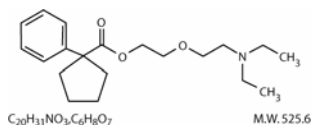
**DESCRIPTION:** Exall™-D Liquid is alcohol-free, dye-free, sugar-free, colorless liquid for oral administration having a fruit gum odor and flavor.

Each teaspoonful (5 mL) for oral administration contains:

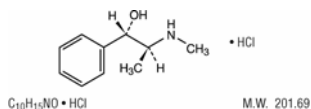
Carbetapentane Citrate.....10 mg  
Pseudoephedrine Hydrochloride.....30 mg  
Guaifenesin..... 100 mg

**Inactive ingredients:** Citric Acid, Fruit Gum Flavor, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

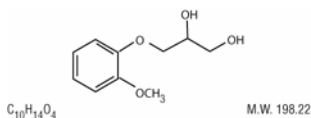
Carbetapentane Citrate (1-Phenylcyclopentanecarboxylic acid 2-(2-diethylaminoethoxy) ethyl ester citrate) is a white crystalline powder. It is freely soluble in water and chloroform. Its structure is as follows:



Pseudoephedrine Hydrochloride is a nasal decongestant with the chemical name Benzenemethanol,  $\alpha$ -[1-(methylamino)ethyl]-, [*S*-(*R*\*,*R*\*)-, hydrochloride. Its structure is as follows:



Guaifenesin (1,2-Propanediol, 3-(2-methoxyphenoxy)-, ( $\pm$ )-) 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. Its structure is as follows:



## CLINICAL PHARMACOLOGY

Antitussive, nasal decongestant, and expectorant actions.

Carbetapentane citrate is a centrally acting non-narcotic antitussive. Carbetapentane citrate has atropine-like and local anesthetic actions, as well as temporarily controls and suppresses the cough reflex by selective depression of the medullary cough center. It has

no significant analgesic or sedative properties, does not depress respiration or pre-dispose to addiction with usual doses.

Pseudoephedrine hydrochloride is an oral sympathomimetic amine that acts as a nasal decongestant to respiratory tract mucous membranes. While its vasoconstrictor action is similar to that of ephedrine, pseudoephedrine has less pressor effect in normotensive adults. Serum half-life for pseudoephedrine is 6 to 8 hours. Acidic urine is associated with faster elimination of the drug. About one-half of the administered dose is excreted in the urine. Pseudoephedrine causes vasoconstriction, which results in reduction of tissue hyperemia, edema, nasal congestion and an increase in nasal airway patency.

Guaifenesin has an expectorant action, which increases the output of respiratory tract fluid by reducing adhesiveness and surface tension. By increasing respiratory tract fluid, guaifenesin reduces the viscosity of secretions, and facilitates expectoration of retained secretions. Guaifenesin is readily absorbed from the gastrointestinal tract and is rapidly metabolized and renally excreted. Guaifenesin has a plasma half-life of one hour. The major urinary metabolite is beta-(2-methoxyphenoxy) lactic acid. Sinus and bronchial drainage is improved and dry, non-productive coughs become more productive and less frequent. Guaifenesin helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, drain bronchial tubes, and make coughs more productive.

#### **INDICATIONS AND USAGE**

For temporary relief of productive and non-productive cough accompanying respiratory tract congestion associated with the common cold, influenza, sinusitis, and bronchitis. For the relief of eustachian tube congestion. For adjunctive therapy in serous otitis media.

#### **CONTRAINDICATIONS**

Exall™-D Liquid is contraindicated in infants and newborns, and in patients with a known hypersensitivity to any of the ingredients and in patients receiving monoamine oxidase inhibitor (MAOI) therapy, including 14 days after stopping.

#### **WARNINGS**

**General:** Before prescribing any medication to suppress or modify cough, it is important that the underlying cause of the cough is identified. Check with physician if cough persists after medication has been used for 7 days or if high fever, skin rash, or continued headache, or sore throat is present with cough. Hypertensive patients should use this product only with medical advice, as they may experience a change in blood pressure due to added vasoconstriction.

Sympathomimetic amines should be used judiciously and sparingly in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism or prostatic hypertrophy. Sympathomimetics may produce central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension.

Do not exceed recommended dosage.

If a hypertensive crisis occurs, these drugs should be discontinued immediately and therapy to lower blood pressure should be instituted. Fever should be managed by means of external cooling.

**Information for Patients:** Patients should be instructed to take Exall™-D Liquid only as prescribed. If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a physician.

**Drug Interactions:** Concurrent use of digitalis glycosides may increase the possibility of cardiac arrhythmias. Sympathomimetics may reduce the hypotensive effects of guanethidine, mecamylamine, methyldopa, reserpine and veratrum alkaloids. Concurrent use of tricyclic antidepressants may antagonize the effects of pseudoephedrine. Use of other vasopressor drugs during halothane anesthesia may cause serious cardiac arrhythmias.

**Drug/Laboratory Test Interactions:** Carbetapentane citrate should not be used in patients receiving MAO inhibitors, including 14 days after stopping the MAOI drug. The use of carbetapentane citrate may result in additive CNS depressant effects when coadministered with alcohol, antihistamines, psychotropics or other drugs that produce CNS depression.

Guaifenesin may produce an increase in urinary 5-hydroxyindoleacetic 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.

Pseudoephedrine has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.). MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines and the overall effects of sympathomimetics agents.

**Carcinogenesis, Mutagenesis, and Impairment of Fertility:** No adequate and well-controlled studies have been conducted to determine whether the components of Exall™-D Liquid 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.

**Pediatric use:** Safety and effectiveness in pediatric patients below the age of six have not been established. Product not intended for administration for children 6 years of age and under.

**Geriatric Use:** Patients aged 60 and older are more likely to experience adverse reactions to sympathomimetics. Overdosage of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression, and death. 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 drug therapy.

### **ADVERSE REACTIONS**

Adverse effects associated with carbetapentane citrate are rare, but nausea and/or other gastrointestinal disturbances sometimes occur.

Hyperreactive individuals may display ephedrine-like reactions such as tachycardia, palpitations, headache, dizziness or nausea. Sympathomimetics have been associated with certain untoward reactions including fear, anxiety, nervousness, restlessness, tremor, weakness, pallor, respiratory difficulty, dysuria, insomnia, hallucinations, convulsions, CNS depression, arrhythmias, and cardiovascular collapse with hypotension.

Guaifenesin is well tolerated and has a wide margin of safety. Side effects are generally mild and infrequent. Nausea and vomiting are the most frequently occurring side effects.

### **OVERDOSAGE**

**Signs and symptoms:** Overdosage with carbetapentane citrate may produce central excitement and mental confusion. Guaifenesin is unlikely to produce toxic effects since its toxicity is low. When laboratory animals were administered guaifenesin in doses up to 5 g/kg by stomach tube, no toxicity resulted.

In large doses, sympathomimetics may give rise to giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness, and tenseness, anxiety, restlessness, and insomnia. Many patients can present a toxic psychosis with delusions and hallucinations. Some may develop cardiac arrhythmias, circulatory collapse, convulsions, coma and respiratory failure.

**Treatment:** Treatment of acute overdosage should be based upon treating the patient for the symptoms of overdosage of pseudoephedrine as follows:

If the amount ingested is considered dangerous or excessive, induce vomiting with ipecac syrup unless the patient is convulsing, comatose, or has lost the gag reflex, in which case perform gastric lavage using a large bore tube. If indicated, follow with activated charcoal and a saline cathartic. 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.

The treatment of overdose should provide symptomatic and supportive care.

**DOSAGE AND ADMINISTRATION**

**Adults and children 12 years of age and older:**

1-2 teaspoonfuls (5-10 mL) every 4-6 hours, not to exceed 8 teaspoonfuls in 24 hours.

**Children 6 to 12 years of age:**

1 teaspoonful (5 mL) every 4-6 hours, not to exceed 4 teaspoonfuls in 24 hours.

**Children under 6 years of age:**

Consult a physician.

**HOW SUPPLIED**

Exall™-D Liquid is supplied as a colorless, fruit gum flavored liquid in 16 fl oz (473 mL) bottles, NDC 63717-555-16, and ½ fl oz (15 mL) samples, NDC 63717-555-99.

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, CONTACT A POISON CONTROL CENTER AND SEEK PROFESSIONAL ASSISTANCE IMMEDIATELY.**

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

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

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

**Rx Only**

**Manufactured for:**

Hawthorn Pharmaceuticals, Inc.,  
Madison, MS 39110

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