

Exall™ Liquid

Rx Only

Antitussive / Expectorant

DESCRIPTION:

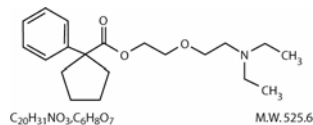
Exall™ Liquid is alcohol-free, dye-free, sugar-free, colorless liquid for oral administration having a cherry odor and flavor.

Each teaspoonful (5 mL) for oral administration contains:

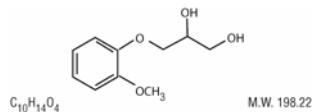
Carbetapentane Citrate..... 10 mg
Guaifenesin..... 100 mg

Inactive ingredients: Cherry Flavor, Citric Acid, 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:



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. Its structure is as follows:



CLINICAL PHARMACOLOGY:

Antitussive 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 predispose to addiction with usual doses.

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.

CONTRAINDICATIONS:

Exall™ 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.

Information for Patients: Patients should be instructed to take Exall™ Liquid only as prescribed. Do not exceed the recommended dose. If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a physician.

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.

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

ADVERSE REACTIONS:

Adverse effects associated with carbetapentane citrate are rare, but nausea and/or other gastrointestinal disturbances sometimes occur. Guaifenesin is well tolerated and has a wide margin of safety. Adverse effects associated with guaifenesin usually result from doses larger than those required for expectoration.

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.

Treatment: The patient should be induced to vomit, even if emesis has occurred spontaneously. Pharmacologic vomiting by the administration of ipecac liquid 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.

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 12 teaspoonfuls in a 24 hour period.

Children 6 to 12 years of age:

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

Children under 6 years of age:

Consult a physician.

HOW SUPPLIED:

Exall™ Liquid is a colorless, cherry flavored liquid and supplied in bottles of 16 fl oz (473 mL), NDC 63717-554-16, or samples of 1/2 fl oz (15 mL), NDC 63717-554-99.

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.

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Manufactured for:

Hawthorn Pharmaceuticals, Inc.
Madison, MS 39110

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