

## Corzall™ Liquid

Rx Only

Antitussive / Decongestant

### DESCRIPTION

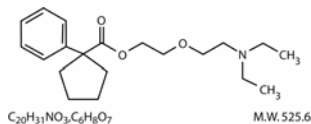
Each teaspoonful (5 mL) for oral administration contains:

Carbetapentane Citrate.....20 mg

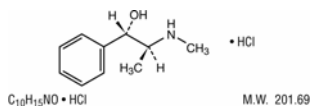
Pseudoephedrine Hydrochloride.....30 mg

**Inactive ingredients:** Citric Acid, Glycerin, Grape Flavor, 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 (Benzenemethanol,  $\alpha$ -[1-(methylamino)ethyl]-, [*S*-(*R*\*,*R*\*)]-, hydrochloride) is the hydrochloride of pseudoephedrine, a naturally occurring dextrorotatory stereoisomer of ephedrine. Its structure is as follows:



### CLINICAL PHARMACOLOGY

Antitussive and decongestant 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.

Pseudoephedrine hydrochloride is an oral sympathomimetic amine that acts as a 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 drug is excreted in the urine.

### INDICATIONS AND USAGE

Corzall™ is indicated for the symptomatic relief of the cough, coryza and nasal congestion associated with the common cold, sinusitis, allergic rhinitis and other upper respiratory tract conditions. Appropriate therapy should be provided for the primary disease.

### CONTRAINDICATIONS

Patients with hypersensitivity or idiosyncrasy to any of its ingredients. Sympathomimetic amines are contraindicated in patients with severe hypertension, severe coronary heart disease and patients on monoamine oxidase (MAO) inhibitor therapy.

## WARNINGS

Sympathomimetic amines should be used judiciously and sparingly in patients with hypertension, diabetes, ischemic heart disease, hyperthyroidism, increased intraocular pressure, or prostatic hypertrophy. (See **CONTRAINDICATIONS**). Sympathomimetic amines may produce CNS stimulation with convulsions or cardiovascular collapse with accompanying hypotension. The elderly (60 years and older) are more likely to exhibit adverse reactions.

A persistent cough may be a sign of a serious condition. If cough persists for more than one week or tends to recur, or is accompanied by fever, rash, or persistent headache, patient re-evaluation should be considered.

## PRECAUTIONS

**General:** There are studies which demonstrate that carbetapentane has antitussive activity which may suppress or modify cough. Before prescribing medication to suppress or modify cough, identify and provide therapy for the underlying cause of the cough and take caution that modification of cough does not increase the risk of clinical or physiologic complications.

Use with caution in patients with hypertension, heart disease, asthma, hyperthyroidism, increased intraocular pressure, diabetes mellitus, and prostatic hypertrophy.

**Information for patients:** Avoid alcohol and other CNS depressants while taking this product. Patients sensitive to sympathomimetics may note mild CNS stimulation.

**Drug 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. 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.

**Pregnancy Category C:** Animal reproduction studies have not been conducted with this product. It is not known whether this product can cause fetal harm when administered to a pregnant woman or affect reproductive capacity. Give to pregnant women only if clearly needed.

**Nursing Mothers:** It is not known if the drugs in this product are excreted in human milk. Since many drugs may be excreted into human milk and because of the potential for serious side effects in the nursing infant, this product should only be given to nursing mothers if clearly needed.

**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:** The elderly (60 years and older) are more likely to have adverse reactions to sympathomimetics. Overdosage of sympathomimetics in this age group may cause hallucinations, convulsions, CNS depression and death.

## ADVERSE REACTIONS

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

**Sympathomimetic Amines:** Convulsions, CNS stimulation, cardiac arrhythmia, respiratory difficulties, increased heart rate or blood pressure, hallucinations, tremors, nervousness, insomnia, pallor and dysuria.

## OVERDOSAGE

The signs, symptoms and treatment described below are those of pseudoephedrine and carbetapentane.

**Symptoms:** Should sympathomimetic symptoms predominate, central effects include restlessness, dizziness, tremor, hyperactive reflexes, talkativeness, irritability, and insomnia. Cardiovascular and renal effects include difficulty in micturition, headache, flushing, palpitation, cardiac arrhythmia, hypertension with subsequent hypotension and circulatory collapse. Gastrointestinal effects include dry mouth, metallic taste, anorexia, nausea, vomiting, diarrhea and abdominal cramps.

### Treatment:

- a) Evacuate stomach as condition warrants. Activated charcoal may be useful.
- b) Maintain a non-stimulating environment.
- c) Monitor cardiovascular status.
- d) Do not give stimulants.
- e) Reduce fever with sponging.
- f) Use sedatives or anticonvulsants to control CNS excitation, and convulsions.
- g) Physostigmine may reverse anti-cholinergic symptoms.
- h) Ammonium Chloride may acidify the urine to increase urinary excretion of pseudoephedrine.
- i) Further care is symptomatic and supportive.

## 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:

1/2 to 1 teaspoonful (2.5-5 mL) every 4-6 hours, not to exceed 6 teaspoonfuls in a 24 hour period.

### Children under 6 years of age:

Consult a physician.

\*In mild cases or in particularly sensitive patients, less frequent or reduced doses may be adequate.

## HOW SUPPLIED

Corzall™ Liquid is supplied as a clear, grape flavored liquid available in 16 fl oz bottles, NDC 63717-552-16 and 1/2 fl oz (15 mL) sample bottles, NDC 63717-552-99.

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

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

Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

Tamper evident by foil seal under cap.

Do not use if foil seal is broken or missing.

### Manufactured for:

Hawthorn Pharmaceuticals, Inc.

Madison, MS 39110

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