

## Corzall™ Plus Liquid

Rx Only

Antitussive / Decongestant / Antihistamine

### DESCRIPTION

Each teaspoonful (5 mL) for oral administration contains:

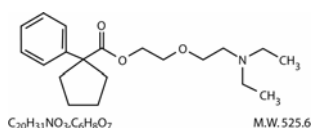
Carbetapentane Citrate..... 20 mg

Pseudoephedrine Hydrochloride..... 30 mg

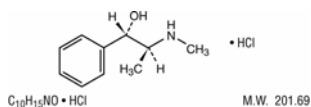
Pyrilamine Maleate..... 7.5 mg

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

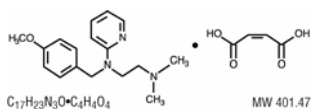
Carbetapentane Citrate (1-Phenylcyclopentanecarboxylic acid, 2-(2-diethylaminoethoxy) ethyl ester citrate) is a white crystalline powder. It is freely soluble in water and chloroform. Its structure is as follows:



Pseudoephedrine Hydrochloride (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:



Pyrilamine Maleate is an antihistamine having the chemical name 2-[[2-Dimethylamino)ethyl] (*p*-methoxybenzyl)amino] pyridine maleate (1:1). Its structural formula is as follows:



### CLINICAL PHARMACOLOGY

Antitussive, decongestant, and antihistaminic 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.

Pyrilamine maleate is a histamine antagonist, specifically an H<sub>1</sub> receptor-blocking agent belonging to the alkylamine class of antihistamines. Antihistamines appear to compete with histamine for receptor sites on effector cells. Pyrilamine also has anticholinergic (drying) and sedative effects. Among the antihistaminic effects, it antagonizes the allergic response (vasodilatation, increased vascular permeability, increased mucus

secretion) of nasal tissue. Pyrilamine is well absorbed from the gastrointestinal tract, with peak plasma concentration after a single, oral dose of 4 mg reached in 5 hours; urinary excretion is the major route of elimination, mostly as products of biodegradation; the liver is assumed to be the main site of metabolic transformation.

## **INDICATIONS AND USAGE**

Corzall™ Plus Liquid 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. Antihistamines are contraindicated in patients with narrow-angle glaucoma, urinary retention, peptic ulcer, and during an asthma attack.

## **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.

Antihistamines may cause hyperexcitability, especially in children. At doses higher than the recommended doses, nervousness, dizziness or sleeplessness may occur. Do not exceed recommended dosage.

## **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 antihistamines may experience moderate to severe drowsiness. 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.

Antihistamines may enhance the effect of tricyclic antidepressants, barbiturates, alcohol, and other CNS depressants. MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines.

Sympathomimetic amines may reduce the antihypertensive effects of reserpine, veratrum alkaloids, methyldopa, and mecamylamine. Effects of sympathomimetics are increased with MAO inhibitors and beta-adrenergic blockers.

**Pregnancy: 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.

**Antihistamines:** Sedation, dizziness, diplopia, vomiting, diarrhea, dry mouth, headache, nervousness, nausea, anorexia, heartburn, weakness, polyuria, and dysuria, and rarely, excitability in children. Urinary retention may occur in patients with prostatic hypertrophy.

**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 H1 antihistamine, pseudoephedrine and carbetapentane.

**Symptoms:** Should antihistamine effects predominate, central action constitutes the greatest danger. In the small child, predominate symptoms are excitation, hallucination, ataxia, incoordination, tremors, flushed face and fever. Convulsions, fixed and dilated pupils, coma, and death may occur in severe cases. In the adult, fever and flushing are uncommon; excitement leading to convulsions and postictal depression is often preceded by drowsiness and coma. Respiration is usually not seriously depressed; blood pressure is usually stable.

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™ Plus Liquid is supplied as a clear, fruit gum flavored liquid available in 16 fl oz bottles, NDC 63717-553-16 and 1/2 fl oz (15 mL) sample bottles, NDC 63717-553-99.

**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

HI 254 08/09