**INDICATIONS AND USAGE**
Carbinoxamine maleate is effective for the symptomatic treatment of:
• Seasonal and perennial allergic rhinitis
• Vasomotor rhinitis
• Allergic conjunctivitis due to inhalant allergens and foods
• Mild, uncomplicated allergic skin manifestations of urticaria and angioedema
• Dermatographism
• As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled
• Amelioration of the severity of allergic reactions to blood or plasma

**CONTRAINDICATIONS**
Carbinoxamine maleate is contraindicated in children younger than 2 years of age.
Carbinoxamine maleate is contraindicated in nursing mothers.
Carbinoxamine maleate is contraindicated in patients who are hypersensitive to the drug or on monoamine oxidase inhibitor therapy (see Drug Interactions).

**WARNINGS**
Deaths have been reported in children less than 2 years of age who were taking antihistamines, including carbinoxamine-containing drug products, therefore, carbinoxamine maleate is contraindicated in children younger than 2 years of age (see CONTRAINDICATIONS). Antihistamines should be used with considerable caution in patients with: narrow angle glaucoma, stenosing peptic ulcer, symptomatic prostatic hypertrophy, bladder neck obstruction, pyloroduodenal obstruction.

**PRECAUTIONS**
General
As many other antihistamines, carbinoxamine maleate has an atropine-like action and, therefore, should be used with caution in patients with: increased intracocular pressure, hyperthyroidism, cardiovascular disease, hypertension.
Antihistamines such as carbinoxamine maleate should not be used to treat lower respiratory tract symptoms, including asthma.

**Drug Interactions**
Monoamine oxidase inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines. Carbinoxamine maleate has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.).

**ADVERSE REACTIONS**
The most frequent adverse reactions are underlined:
Body as a whole: Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and throat
Cardiovascular: Hypotension, headache, palpitations, tachycardia, extrasystoles
Hematologic: Hemolytic anemia, thrombocytopenia, agranulocytosis
Central nervous system: Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, incoordination, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions
Gastrointestinal: Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation
Respiratory: Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

**FIRST-GENERATION ANTIHISTAMINE WITH ANTICHOLINERGIC AND SEDATIVE PROPERTIES**

**CARBINOXAMINE MALEATE TABLETS, USP IMPORTANT SAFETY INFORMATION**
Amelioration of the severity of allergic reactions to blood or plasma.

CONTRAINDICATIONS
Carbinoxamine maleate is contraindicated in children younger than 2 years of age.
Carbinoxamine maleate is contraindicated in nursing mothers.
Carbinoxamine maleate is contraindicated in patients who are hypersensitive to the drug or on monoxamine oxide inhibitor therapy (see Drug Interactions).

WARNINGS
Deaths have been reported in children less than 2 years of age who were taking antihistamines, including carbinoxamine-containing drug products, therefore, carbinoxamine maleate is contraindicated in children younger than 2 years of age (see CONTRAINDICATIONS). Antihistamines should be used with considerable caution in patients with: narrow angle glaucoma, stenosing peptic ulcer, symptomatic prostatic hypertrophy, bladder neck obstruction, pyloroduodenal obstruction.

PRECAUTIONS
General
As many other antihistamines, carbinoxamine maleate has an atropine-like action and, therefore, should be used with caution in patients with: increased intracranial pressure, hyperthyroidism, cardiovascular disease, hypertension. Antihistamines such as carbinoxamine maleate should not be used to treat lower respiratory tract symptoms, including asthma.

Information for Patients
Carbinoxamine maleate may cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery.

Drug Interactions
Monoamine oxidase inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines. Carbinoxamine maleate has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.).

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term studies in animals have been performed to determine the possible effects of carbinoxamine maleate on carcinogenesis, mutagenesis, and fertility.

Pregnancy

Teratogenic Effects
Pregnancy Category C
Animal reproductive studies have not been conducted with carbinoxamine maleate. It is also not known whether carbinoxamine maleate can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Carbinoxamine maleate should be given to a pregnant woman only if clearly needed.

Nursing Mothers
Because of the higher risk of antihistamines for infants and neonates, for newborns and premature in particular, use of carbinoxamine maleate is contraindicated in nursing mothers (see CONTRAINDICATIONS).

Adverse Effects
Cardiac effects, including prolongation of QT interval have not been adequately studied. Unlike other newer antihistamines, severe adverse cardiovascular effects are uncommon, and usually limited to overdosage situations.

Special Populations
Pediatric Patients
Carbinoxamine should not be used in patients with hypersensitivity to carbinoxamine. Carbinoxamine may increase the effects of other drugs such as barbiturates, TCAs, MAO inhibitors such as Phenelzine (Nardil), Tranylcypromine (Parnate), or Selegiline (Eldepryl), alcohol, other antihistamines, and CNS depressants. Carbinoxamine can be taken with or without food.

Gastrointestinal Effects
Carbinoxamine maleate is contraindicated in nursing mothers. Carbinoxamine maleate should be given to a pregnant woman only if clearly needed.

CONTRAINDICATIONS
Carbinoxamine maleate is contraindicated in children younger than 2 years of age (see CONTRAINDICATIONS).

Carbinoxamine maleate should be taken on an empty stomach with water.

DOSAGE AND ADMINISTRATION
Carbinoxamine maleate is contraindicated in children younger than 2 years of age (see CONTRAINDICATIONS).

Carbinoxamine maleate should be taken on an empty stomach with water.

HOW SUPPLIED
Carbinoxamine maleate tablets, USP 6 mg are supplied as a white, round tablet, debossed “404” on one side and “ADG” on the other side, in bottles of 20 tablets, NDC 69067-240-20, and bottles of 100 tablets, NDC 69067-240-10. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Dispense in a tight, light-resistant container with a child-resistant closure as defined by the official compendium.

Manufactured for:
Foxland Pharmaceuticals, Inc.
Trussville, AL 35173