CARBINOXAMINE MALEATE - carbinoxamine maleate tablet
CARBINOXAMINE MALEATE - carbinoxamine maleate solution
Boca Pharmacal, LLC

Carbinoxamine Maleate Tablets USP, 4mg

DESCRIPTION

Carbinoxamine maleate is a histamine-H1 receptor blocking agent.

Each tablet contains 4 mg carbinoxamine maleate.

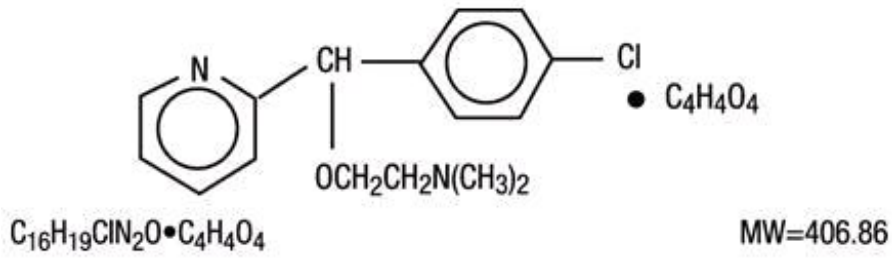
Inactive ingredients: anhydrous lactose, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate.

Each 5 mL (teaspoonful) of oral solution contains 4 mg carbinoxamine maleate.

Inactive ingredients: artificial banana bubble gum flavor, citric acid (anhydrous), glycerin, purified water, sodium benzoate and sorbitol solution.

Carbinoxamine maleate is freely soluble in water.

Its structure is:



2-[(4-chlorophenyl)-2-pyridinylmethoxy]-N, N-dimethylethanamine (Z)-2-butenedioate (1:1)

CLINICAL PHARMACOLOGY

Carbinoxamine maleate is an antihistamine with anticholinergic (drying) and sedative properties. Antihistamines appear to compete with histamine for receptor sites on effector cells.

The pharmacological effects of carbinoxamine maleate after oral absorption have been shown to last approximately 4 hours.

Interactions of carbinoxamine maleate with food or with other drugs and the possibility of cardiac conduction effects on the QT interval have not been studied.

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 section.)

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 with many other antihistamines, carbinoxamine maleate has an atropine-like action and, therefore, should be used with caution in patients with: increased intraocular 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

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 generally and for newborns and prematures in particular, use of carbinoxamine maleate is contraindicated in nursing mothers (see CONTRAINDICATIONS section).

Pediatric Use

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

Carbinoxamine maleate may diminish mental alertness in children. In the young child, particularly, they may produce excitation.

Geriatric Use

Carbinoxamine maleate is more likely to cause dizziness, sedation, and hypotension in elderly patients (approximately 60 years or older). Sedating drugs may also cause confusion and over sedation in the elderly. Therefore, 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 other drug therapy.

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, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions.

Gastrointestinal: Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.

Urogenital: Urinary frequency, difficult urination, urinary retention, early menses.

Respiratory: Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

OVERDOSAGE

Manifestations: Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms – dry mouth; fixed, dilated pupils; flushing; and gastrointestinal symptoms may also occur. Especially in infants and children, antihistamine overdosage may cause hallucinations, convulsions, or death.

The oral LD50 of carbinoxamine maleate in guinea pigs is 411 mg/kg.

Treatment: The treatment of overdosage with carbinoxamine maleate is essentially symptomatic and supportive. Vital signs (including respiration, pulse, blood pressure, and temperature) and EKG should

be monitored. Induction of vomiting is not recommended. Activated charcoal should be given and gastric lavage should be considered after ingestion of a potentially life-threatening amount of drug.

In the presence of severe anticholinergic effects, physostigmine may be useful. Vasopressors may be used to treat hypotension.

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.

DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND THE RESPONSE OF THE PATIENT.

Carbinoxamine maleate dosage should be based on the severity of the condition and the response of the patient. The drug is well tolerated in adult doses as high as 24 mg daily, in divided doses, over prolonged periods. On the other hand, some patients respond to as little as 4 mg daily.

Clinical experience suggests the following dosage schedules:

Tablets

Usual Adult Dosage:

1 or 2 tablets (4 to 8 mg) 3 to 4 times daily.

Usual Child's Dosage:

Six to eleven years – 1/2 to 1 tablet (2 to 4 mg) 3 to 4 times daily.

Oral Solution

Usual Adult Dosage:

1 or 2 teaspoonfuls (4 to 8 mg) 3 to 4 times daily.

Usual Child's Dosage:

(approximately 0.2 to 0.4 mg/kg/day, divided into 3 to 4 doses):

Six to eleven years – 1/2 to 1 teaspoonful (2 to 4 mg) 3 to 4 times daily.

Dosing for children 2 to 5 years of age should be based on weight whenever possible. The usual dosage for children 2 to 5 years of age is approximately 0.2 to 0.4 mg/kg/day, divided into 3 to 4 daily doses. In general, this corresponds to a dose of 1/4 to 1/2 teaspoonful (1 to 2 mg) 3 to 4 times daily.

HOW SUPPLIED

Carbinoxamine Maleate Tablets USP, 4 mg are supplied as white, round tablets scored and debossed "B" bisected "P" on one side and "605" on the other side, and supplied in bottles of 100 tablets, NDC 64376-605-01.

Carbinoxamine Maleate Oral Solution, 4 mg/5 mL is supplied as clear, colorless liquid with a banana bubble gum flavor, and is supplied in 4 oz bottles NDC 64376-612-40 and 16 oz bottles NDC 64376-612-16.

Storage and Handling

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

Dispense in a tight, light-resistant container with a child-resistant closure as defined in the official compendium.

Manufactured for:

Boca Pharmacal, LLC

Coral Springs, FL 33065

www.bocapharmacal.com

1-800-354-8460

Rev. 08/13

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 64376-605-01

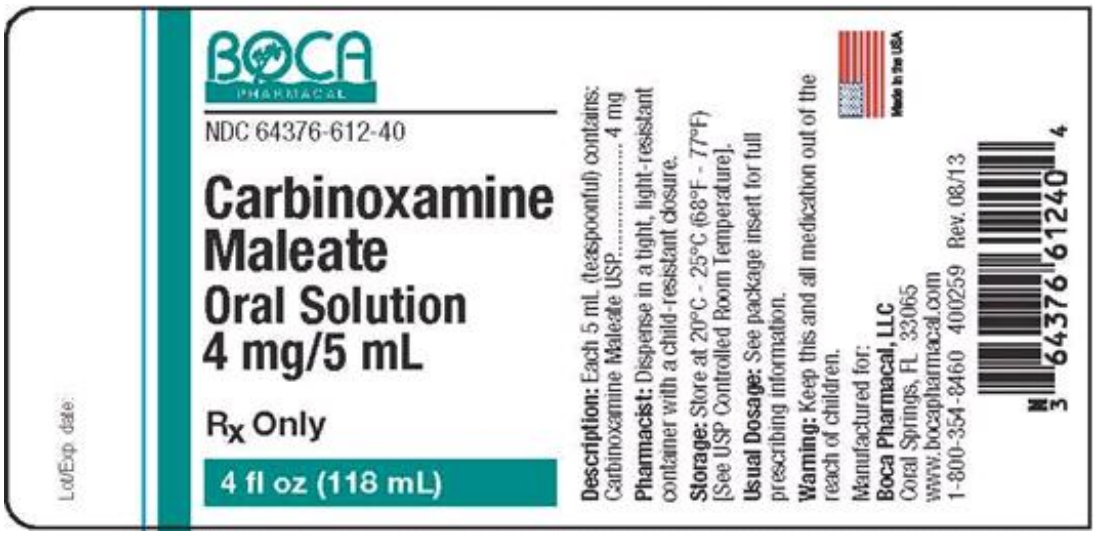
4mg/Tablet 100-count Bottle

[Rev. 4]

NDC: 64376-612-40

4mg/5mL 4 fl oz Bottle

[Rev. 10]



NDC: 64376-612-16

4mg/5mL 16 fl oz Bottle

[Rev. 13]

CARBINOXAMINE MALEATE

carbinoxamine maleate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64376-605
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARBINOXAMINE MALEATE (UNII: 02O55696WH) (CARBINOXAMINE - UNII:982A7M02H5)	CARBINOXAMINE MALEATE	4 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	BP;605
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64376-605-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040639	05/30/2008	

CARBINOXAMINE MALEATE

carbinoxamine maleate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64376-612
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARBINOXAMINE MALEATE (UNII: 02O55696WH) (CARBINOXAMINE - UNII:982A7M02H5)	CARBINOXAMINE MALEATE	4 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ISOAMYL ACETATE (UNII: Z135787824)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	BANANA (artificial banana gum flavor)	**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64376-612-40	118 mL in 1 BOTTLE		
2	NDC:64376-612-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040814	02/26/2008	

Labeler - Boca Pharmacal, LLC (170266089)

Registrant - Boca Pharmacal, LLC (170266089)

Revised: 9/2013 Boca Pharmacal, LLC