CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 40-458

APPROVED LABELING

STORAGE: Store at controlled room temperature, 15°C to 30°C (59°F to 86°F) (See USP).

WARNING: Keep this and all medications out of the reach of children.

NDC 0525-6748-30

Carbinoxamine Maleate Oral Solution, 4 mg/5 mL

℞ only

PROFESSIONAL SAMPLE: NOT FOR SALE

Each 5 mL (teaspoonful) contains:
Carbinoxamine Maleate, USP ..... 4 mg

Contents: 1 fl oz (30 mL)

USUAL DOSAGE: See package insert for full prescribing information.

Manufactured For:
Pamlab L.L.C.
Covington, LA 70433

Manufactured By:
MIKART, INC.
Atlanta, GA 30318

Code 892A01
Rev. 01/03

Lot No.:
Exp. Date:

PHARMACIST: Dispense in a tight, light-resistant container with a child-resistant closure.

STORAGE: Store at controlled room temperature, 15°C to 30°C (59°F to 86°F) (See USP).

NDC 0525-6748-04

Carbinoxamine Maleate Oral Solution, 4 mg/5 mL

℞ only

Each 5 mL (teaspoonful) contains:
Carbinoxamine Maleate, USP ..... 4 mg

Contents: 4 fl oz (118 mL)

USUAL DOSAGE: See package insert for full prescribing information.

WARNING: Keep this and all medications out of the reach of children.

Manufactured For:
Pamlab L.L.C.
Covington, LA 70433

Manufactured By:
MIKART, INC.
Atlanta, GA 30318

Code 892A04
Rev. 01/03

Lot No.:
Exp. Date:

PHARMACIST: Dispense in a tight, light-resistant container with a child-resistant closure.

STORAGE: Store at controlled room temperature, 15°C to 30°C (59°F to 86°F) (See USP).

NDC 0525-6748-16

Carbinoxamine Maleate Oral Solution, 4 mg/5 mL

℞ only

Each 5 mL (teaspoonful) contains:
Carbinoxamine Maleate, USP ..... 4 mg

Contents: 16 fl oz (473 mL)

USUAL DOSAGE: See package insert for full prescribing information.

WARNING: Keep this and all medications out of the reach of children.

Manufactured For:
Pamlab L.L.C.
Covington, LA 70433

Manufactured By:
MIKART, INC.
Atlanta, GA 30318

Code 892A16 Rev. 01/03

Lot No.:
Exp. Date:

05256748

Carbinoxamine Maleate Oral Solution, 4 mg/5 mL

℞ only

Code 892A00 Rev. 01/03

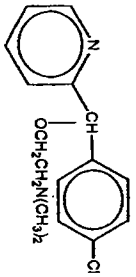
APR 25 2003

APPROVED

DESCRIPTION:
Carbinoxamine maleate is a histamine-H_1 receptor blocking agent.

Each 5 mL (teaspoonful) contains 4 mg carbinoxamine maleate, USP.

Carbinoxamine maleate is freely soluble in water. Its structure is:



•

2-[(4-chlorophenyl)-2-pyridinyl-methoxy]-*N, N*-dimethylethanamine (Z)-2-butenedioate (1:1)

$C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$ MW=406.86

Inactive ingredients: artificial bubble gum flavor, citric acid (anhydrous), glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate (hydrous) and sorbitol solution.

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.

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 patients who are hypersensitive to the drug or on monoamine oxidase inhibitor therapy. (See Drug Interactions section.)

Antihistamines such as carbinoxamine maleate should not be used in newborn or premature infants.

Antihistamines such as carbinoxamine maleate should not be used to treat lower respiratory tract symptoms, including asthma.

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.

WARNINGS:
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:
As other antihistamines, carbinoxamine maleate has an atropine-like action and, therefore, should be used with caution in patients with: history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, hypertension. Antihistamines may diminish mental alertness in children. In the young child, particularly, they may produce excitation.

Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients (approximately 60 years or older).

Information for Patients: Patients should be warned about engaging in activities requiring mental alertness, as driving a car or operating machinery, etc.

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: (see CONTRAINDICATIONS section)

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 LD_{50} of carbinoxamine maleate in guinea pigs is 411 mg/kg.

Treatment: *If vomiting has not occurred spontaneously,* the patient should be induced to vomit. This is best done by having him drink a glass of water or milk, after which he should be made to gag. Precautions against aspiration must be taken, especially in infants and children.

If the attempt to induce vomiting is unsuccessful, gastric lavage is indicated within 3 hours after ingestion and even later if large amounts of milk or cream were given beforehand. Isotonic or ½ isotonic saline is the lavage solution of choice.

Saline cathartics, as milk of magnesia, by osmosis draw water into the bowel and, therefore, are valuable for their action in rapid dilution of bowel content.

Stimulants should not be used.

Vasopressors may be used to treat hypotension.

DOSAGE AND ADMINISTRATION:
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 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:

Usual Adult Dosage:
1 or 2 teaspoonfuls (4 to 8 mg) 3 to 4 times daily

Usual Child's Dosage (approximately 0.2 – 0.4 mg/kg/day):
One to three years – ¼ teaspoonful (2 mg) 3 or 4 times daily.
Three to six years – ½ teaspoonful to 1 teaspoonful (2 to 4 mg) 3 or 4 times daily
Over six years -- 1 to 1½ teaspoonfuls (4 to 6 mg) 3 or 4 times daily.

HOW SUPPLIED:
Carbinoxamine Maleate Oral Solution, 4 mg/5 mL is supplied as clear, colorless liquid with a bubble gum aroma, and is supplied in 4 oz bottles NDC 0525-6748-04 and 16 oz bottles NDC 0525-6748-16.

Store at controlled room temperature, 15°C to 30°C (59°F to 86°F) [See USP].

Dispense in a tight, light-resistant container with a child-resistant closure.

Manufactured for:
Pamlab, L.L.C.
Covington, LA 70433

Manufactured by:
MIKART, INC.
Atlanta, GA 30318

Code 892A00 Rev. 01/03

ENLARGED TO 129%