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.

Carboxinomaleate Oral Solution, 4 mg/5 mL

Rx only

PROFESSIONAL SAMPLE: NOT FOR SALE

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

Contents: 1 fl oz (30 mL)

NDC 0525-6748-30

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

Carboxinomaleate Oral Solution, 4 mg/5 mL

Rx only

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

Contents: 4 fl oz (118 mL)

NDC 0525-6748-04

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

Carboxinomaleate Oral Solution, 4 mg/5 mL

Rx only

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

Contents: 16 fl oz (473 mL)

NDC 0525-6748-16

USUAL DOSAGE: See package insert for full prescribing information.

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

Manufactured For:
Pamlab, Inc.
Covington, LA 70433

Manufactured By:
MIKART, INC.
Atlanta, GA 30318

Code 892A04
Rev. 01/03

USUAL DOSAGE: See package insert for full prescribing information.

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

Manufactured For:
Pamlab, Inc.
Covington, LA 70433

Manufactured By:
MIKART, INC.
Atlanta, GA 30318

Code 892A16
Rev. 01/03
INDICATIONS AND USAGE:
Carboxinomine maleate is effective for the symptomatic treatment of:

- Seasonal and perennial allergic rhinitis.
- Vasomotor rhinitis.

Allergic conjunctivitis due to inhalant allergens and foods.

Mei, uncomplicated allergic skin manifestations of urticaria and angioedema.

Dermatographism. As therapy for anaphylactic reactions adjunctive to epinephrine and other systemic agents after the acute manifestations have been controlled.

Amelioration of the severity of allergic reactions to blood or plasma.

CONTRAINDICATIONS:
Carboxinomine maleate is contraindicated in patients who are sensitive to the drug or on an antihistamine, antacid, or aspirin therapy. (See Drug Interactions section.)

Antihistamines such as carboxinomine maleate should not be used in newborns or premature infants. Antihistamines such as carboxinomine maleate should not be used to treat lower respiratory tract symptoms, including asthma.

Because of the higher risk of antihistamines in infants generally and for newborns and premature infants, use of carboxinomine maleate is contraindicated in nursing mothers.

WARNINGS:
Antihistamines should be used with considerable caution in patients with: narrowing of glaucoma, stenosing peptic ulcer, symptomatic prostatic hypertrophy, bladder neck obstruction, and pyloroduodenal obstruction.

PRECAUTIONS:
As other antihistamines, carboxinomine maleate has an atropine-like action and, therefore, should be used with caution in patients with history of bronchial asthma, increased intracranial pressure, hyperpyrexia, cardiovascular disease, or 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 (dry) effects of antihistamines.

Carboxinomine 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 carboxinomine maleate on carcinogenesis, mutagenesis, and fertility.

OVERDOSAGE:
Manifestations: Antihistamine overdose 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 carboxinomine 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 10% isotonic saline is the lavage solution of choice.

Safety inhalation, as milk of magnesia, by osmotic draw water into the bowel and, therefore, are valuable for their action in rapid dilution of bowel content.

Stimulants should not be used. Vasoconstrictors may be used to treat hypotension.

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

Carboxinomine maleate dosage should be based on 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 schedule:

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):
One to three years - 1 teaspoonful (7 mg) or 3 or 4 times daily.
Three to six years - 2 teaspoonfuls (15 mg) or 3 or 4 times daily.
Six years to 12 years - 2 to 3 teaspoonfuls (15 to 22.5 mg) or 3 or 4 times daily.

HOW SUPPLIED:
Carboxinomine Maleate Oral Solution, 4 mg/5 mL, is supplied as a clear, colorless liquid with a bubble gum aroma, and is supplied in 4 oz bottles NDC 0295-6748-04 and 16 oz bottles NDC 0295-6748-16.

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:
Parke, D. & E. Co., Inc., Co., N.J.
Manufactured By:
MIKARI, INC., Atlanta, GA 30338

Code 892-400
Rev. 01/03

ENLARGED TO 120%