RYCLORA- dexchlorpheniramine maleate liquid
CARWIN PHARMACEUTICAL ASSOCIATES, LLC

RYCLORA™
(dexchlorpheniramine maleate) Oral Solution, USP

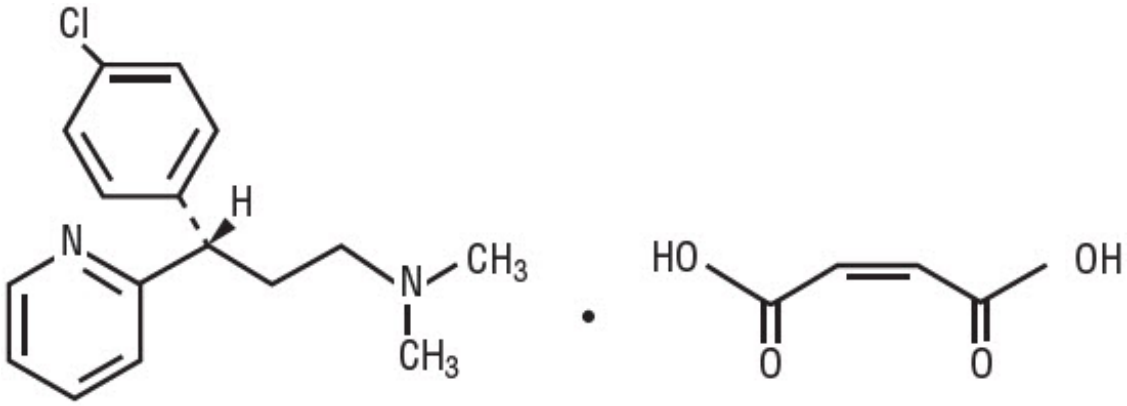
Rx only

DESCRIPTION

Each 5 mL (teaspoonful) contains:

Dexchlorpheniramine Maleate, USP	2 mg

Dexchlorpheniramine Maleate, USP, an antihistamine agent, is a white, odorless crystalline powder that is freely soluble in water. The molecular formula is $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$, designated chemically as (+)-2-[p-Chloro-α-[2-(dimethylamino)ethyl]benzyl] pyridine maleate (1:1).



M.W. = 390.86

Inactive Ingredients: Citric acid, cherry flavoring, FD&C Red No. 40, glycerin, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate dihydrate, and sugar.

CLINICAL PHARMACOLOGY

Dexchlorpheniramine maleate is an antihistamine with anticholinergic (drying) and sedative side effects. Antihistamines appear to compete with histamine for cell receptor sites on effector cells.

INDICATIONS AND USAGE

Perennial and seasonal allergic rhinitis

Vasomotor rhinitis

Allergic conjunctivitis due to inhalant allergens and foods

Mild, uncomplicated allergic skin manifestations of urticaria and angioedema

Amelioration of allergic reactions to blood or plasma

Dermographism

As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.

CONTRAINDICATIONS

Use in Newborn or Premature Infants

This drug should not be used in newborn or premature infants.

Use in Nursing Mothers

Because of the higher risk of antihistamines for infants generally and for newborns and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

Use in Lower Respiratory Disease

Antihistamines **should NOT** be used to treat lower respiratory tract symptoms including asthma.

Antihistamines are also contraindicated in the following conditions:

Hypersensitivity to dexchlorpheniramine maleate or other antihistamines of similar chemical structure
Monoamine oxidase inhibitor therapy (See Drug Interaction section)

WARNINGS

Antihistamines should be used with considerable caution in patients with:

Narrow angle glaucoma
Stenosing peptic ulcer
Pyloroduodenal obstruction
Symptomatic prostatic hypertrophy
Bladder neck obstruction

Use in Children

In infants and children, especially, antihistamines in **overdosage** may cause hallucinations, convulsions, or death.

As in adults, antihistamines may diminish mental alertness in children. In the young child, particularly, they may produce excitation.

Use in Pregnancy

Experience with this drug in pregnant women is inadequate to determine whether there exists a potential for harm to the developing fetus.

Use with CNS Depressants

RYCLORA™ Oral Solution has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.).

Use in Activities Requiring Mental Alertness

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

Use in the Elderly (approximately 60 years or older)

Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients.

PRECAUTIONS

RYCLORA™ Oral Solution 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

Drug Interaction

MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

ADVERSE REACTIONS

1. **General:** Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose and the throat.
2. **Cardiovascular System:** Hemolytic anemia, thrombocytopenia, agranulocytosis.
3. **Hematologic System:** Hemolytic anemia, thrombocytopenia, agranulocytosis.
4. **Nervous System:** Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesias, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, hysteria, neuritis, convulsions.
5. **G.I. System:** Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
6. **G.U. System:** Urinary frequency, difficult urination, urinary retention, early menses.
7. **Respiratory System:** Thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

Call your doctor for medical advice about side effects. You may voluntarily report side effects to FDA at 1-800-FDA-1088. Questions or comments? Call Carwin Pharmaceutical Associates, LLC at 1-844-700-5011.

OVERDOSAGE

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.

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

Saline cathartics, such as milk of magnesia, draw water into the bowel by osmosis 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.

Recommended Dosage

Adults and Children 12 years of age and older: 2 mg (1 teaspoonful)

Children 6 to 11 years: 1 mg (1/2 teaspoonful)

Children 2 to 5 years: 0.5 mg (1/4 teaspoonful)

Doses are generally given every 4 to 6 hours.

HOW SUPPLIED

RYCLORA™ Oral Solution is supplied as a red colored, cherry flavored liquid in the following sizes:

4 fl oz (118 mL), NDC 15370-150-04
16 fl oz (473 mL), NDC 15370-150-16
0.7 fl oz (20mL), NDC 15370-150-99 (as physician sample)

RECOMMENDED STORAGE

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, with child-resistant closure.

Rx Only

Manufactured for:
Carwin Pharmaceutical Associates, LLC
Hazlet, NJ 07730

www.carwinpharma.com

500403-01

REV. 03/2018

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 15370-150-16

RyClora™
(dexchlorpheniramine maleate)

Oral Solution, USP
2 mg/5 mL

Cherry Flavor

Rx Only
16 fl. oz (473 mL)

carwin
PHARMACEUTICAL ASSOCIATES

NDC 15370-150-16

RyClora™

(dexchlorpheniramine maleate)

Oral Solution, USP
2 mg/5 mL

Cherry Flavor

Rx Only 16 fl. oz (473 mL)

carwin PHARMACEUTICAL ASSOCIATES

N 3 1537-0150-16 4

DO NOT USE IF INNER FOIL SEAL IS BROKEN OR MISSING

Each 5 mL (teaspoonful) contains:
Dexchlorpheniramine Maleate, USP ..... 2 mg

Usual Dosage: See package insert for full prescribing information.

Pharmacist: Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure.

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

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.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured for:
Carwin Pharmaceutical Associates, LLC
Hazlet, NJ 07730

www.carwinpharma.com
400727-05 Iss. 03/18

RYCLORA
dexchlorpheniramine maleate liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:15370-150
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

Dexchlorpheniramine Maleate (UNII: B10YD955QW) (Dexchlorpheniramine - UNII:3Q9Q0B929N)	Dexchlorpheniramine Maleate	2 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
menthol, unspecified form (UNII: L7T10EIP3A)	
methylparaben (UNII: A2I8C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
trisodium citrate dihydrate (UNII: B22547B95K)	
sucrose (UNII: C151H8M554)	

Product Characteristics

Color	RED	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15370-150-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/07/2018	
2	NDC:15370-150-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/07/2018	
3	NDC:15370-150-99	20 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/07/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202520	10/07/2018	

Labeler - CARWIN PHARMACEUTICAL ASSOCIATES, LLC (079217215)

Revised: 1/2024 CARWIN PHARMACEUTICAL ASSOCIATES, LLC