POLMON- dexchlorpheniramine maleate solution
Capellon Pharmaceuticals, LLC

POLMON

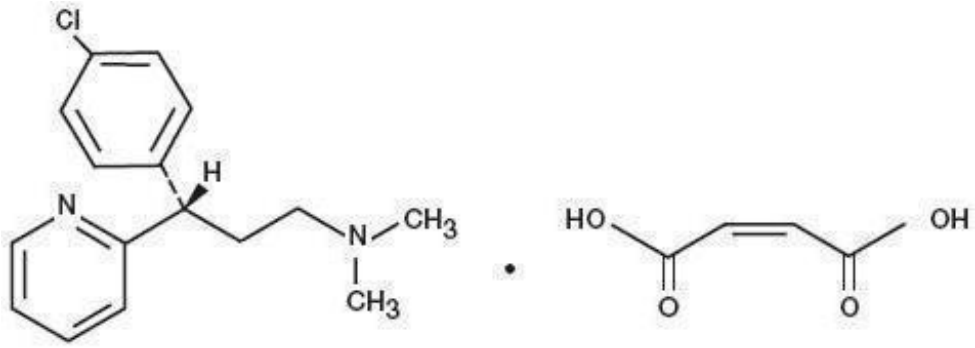
(Dexchlorpheniramine Maleate Oral Solution, USP)

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:

POLMON 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

POLMON 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.

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

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

4 fl oz (118 mL), NDC 64543-600-04
16 fl oz (473 mL), NDC 64543-600-16

Storage and Handling

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

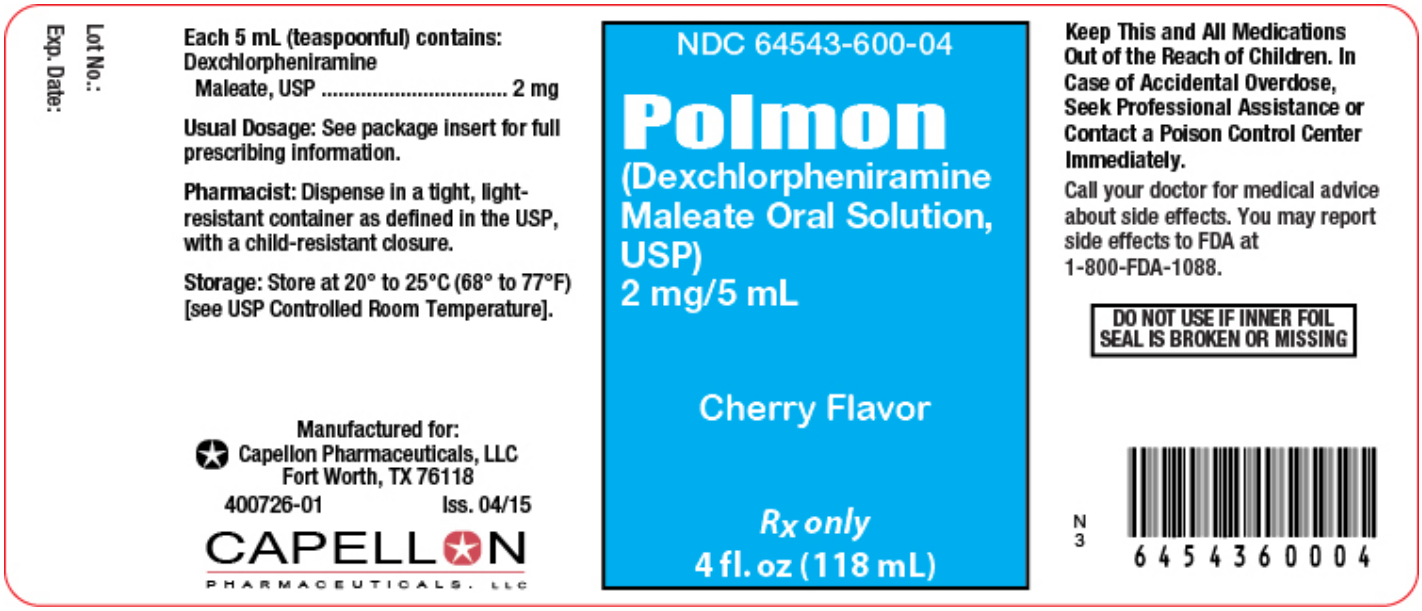
Manufactured For:
Capellon Pharmaceuticals, LLC
Fort Worth, TX 76118

CAPELLON
PHARMACEUTICALS, LLC

500403-01

REV. 04/2015

Principal Display Panel-4 fl oz. Bottle



4 fl oz. Bottle Label

NDC 64543-600-04

POLMON
(dexchlorpheniramine maleate oral solution, USP)
2 mg per 5 mL

Rx Only

4 fl oz. (118 mL)

USUAL DOSAGE: See Package Insert for Complete Dosage Recommendations.
Dispense in a tight, light-resistant container with a child-resistant closure.

WARNING: KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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

Tamper evident by foil seal under cap. Do not use if inner foil seal is broken or missing.

Manufactured for:
Capellon Pharmaceuticals, LLC
Fort Worth, TX 76118

16 fl oz. Bottle Label

NDC 64543-600-16

POLMON
(dexchlorpheniramine maleate oral solution, USP)
2 mg per 5 mL

Rx Only

16 fl oz. (473 mL)

USUAL DOSAGE: See Package Insert for Complete Dosage Recommendations. Dispense in a tight, light-resistant container with a child-resistant closure.

WARNING: KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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

Tamper evident by foil seal under cap. Do not use if inner foil seal is broken or missing.

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64543-600
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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:64543-600-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2018	10/05/2024
2	NDC:64543-600-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2018	10/05/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202520	07/16/2018	10/05/2024

Labeler - Capellon Pharmaceuticals, LLC (124568093)

Revised: 8/2023 Capellon Pharmaceuticals, LLC