

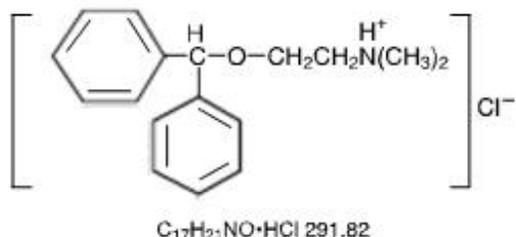
**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride solution**  
**Medical Purchasing Solutions, LLC**

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**Diphenhydramine Hydrochloride Oral Solution USP**

**Rx ONLY**

**DESCRIPTION**

Diphenhydramine hydrochloride is an antihistamine drug having the chemical name 2-(diphenylmethoxy)-N,N -dimethylethylamine hydrochloride and has the molecular formula  $C_{17}H_{21}NO \cdot HCl$  (molecular weight 291.82). It occurs as a white odorless, crystalline powder and is freely soluble in water and alcohol. The structural formula is as follows:



Each 5 mL contains 12.5 mg of diphenhydramine hydrochloride and alcohol 14% for oral administration. Inactive Ingredients: Citric acid, D&C Red No. 33, FD&C Red No. 40, flavoring, purified water, sodium citrate, and sucrose.

**CLINICAL PHARMACOLOGY**

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

A single oral dose of diphenhydramine hydrochloride is quickly absorbed with maximum activity occurring in approximately one hour. The duration of activity following an average dose of diphenhydramine hydrochloride is from four to six hours.

Diphenhydramine is widely distributed throughout the body, including the CNS. Little, if any, is excreted unchanged in the urine; most appears as the degradation products of metabolic transformation in the liver, which are almost completely excreted within 24 hours.

**INDICATIONS AND USAGE**

Diphenhydramine hydrochloride in the oral form is effective for the following indications:

**Antihistaminic**

For allergic conjunctivitis due to foods; mild, uncomplicated allergic skin manifestations of urticaria and angioedema; amelioration of allergic reactions to blood or plasma; dermatographism; as therapy for anaphylactic reactions *adjunctive* to epinephrine and other standard measures after the acute manifestations have been controlled.

### **Motion Sickness**

For active and prophylactic treatment of motion sickness.

### **Antiparkinsonism**

For parkinsonism (including drug-induced) in the elderly unable to tolerate more potent agents; mild cases of parkinsonism (including drug-induced) in other age groups; in other cases of parkinsonism (including drug-induced) in combination with centrally acting anticholinergic agents.

### **Nighttime Sleep-aid.**

## **CONTRAINDICATIONS**

### **Use in Neonates or Premature Infants**

This drug should *not* be used in neonates or premature infants.

### **Use in Nursing Mothers**

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

### **Antihistamines are also contraindicated in the following conditions**

Hypersensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure.

## **WARNINGS**

Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder-neck obstruction.

### **Use in Pediatric Patients**

In pediatric patients, especially, antihistamines in *overdosage* may cause hallucinations, convulsions, or death. As in adults, antihistamines may diminish mental alertness in pediatric patients. In the young pediatric patient, particularly, they may produce excitation.

### **Use in the Elderly (approximately 60 years or older)**

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

## **PRECAUTIONS**

### **General**

Diphenhydramine hydrochloride has an atropine-like action and therefore, should be used with caution in patients with a history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease or hypertension. Use with caution in patients with lower respiratory disease including asthma.

### **Information for Patients**

Patients taking diphenhydramine hydrochloride should be advised that this drug may cause drowsiness and has an additive effect with alcohol. Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.

### **Drug Interactions**

Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.). MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies in animals to determine mutagenic and carcinogenic potential have not been performed.

### **Pregnancy**

Pregnancy Category B

Reproduction studies have been performed in rats and rabbits at doses up to 5 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to diphenhydramine hydrochloride. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

### **Pediatric Use**

Diphenhydramine hydrochloride should not be used in neonates and premature infants (see CONTRAINDICATIONS).

Diphenhydramine hydrochloride may diminish mental alertness, or, in the young pediatric patient, cause excitation. Overdosage may cause hallucinations, convulsions, or death (see WARNINGS and OVERDOSAGE).

See also DOSAGE AND ADMINISTRATION section.

## **ADVERSE REACTIONS**

**The most frequent adverse reactions are underscored.**

1. *General:* Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive

- perspiration, chills, dryness of the mouth, nose and throat.
2. *Cardiovascular System:* Hypotension, headache, palpitations, tachycardia, extrasystoles.
  3. *Hematologic System:* Hemolytic anemia, thrombocytopenia, agranulocytosis.
  4. *Nervous System:* Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, neuritis, convulsions.
  5. *GI System:* Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
  6. *GU System:* Urinary frequency, difficult urination, urinary retention, early menses.
  7. *Respiratory System:* Thickening of bronchial secretions, tightness of chest or throat and wheezing, nasal stuffiness.

To report SUSPECTED ADVERSE REACTIONS, contact Pharmaceutical Associates, Inc. at 1-800-845-8210 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

## **OVERDOSAGE**

Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in pediatric patients. 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 him drink a glass of water or milk after which he should be made to gag. Precaution against aspiration must be taken, especially in infants and children.

*If 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 1/2 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.

A single oral dose of diphenhydramine hydrochloride is quickly absorbed with maximum activity occurring in approximately one hour. The duration of activity following an average dose of diphenhydramine hydrochloride is from four to six hours.

### **Adults**

25 to 50 mg three to four times daily. The nighttime sleep aid dosage is 50 mg at bedtime.

## **Pediatric Patients (over 20 lbs.)**

12.5 to 25 mg three or four times daily. Maximum daily dosage not to exceed 300 mg. For physicians who wish to calculate the dose on the basis of body weight or surface area, the recommended dosage is 5 mg/kg/24 hours or 150 mg/m<sup>2</sup>/24 hours.

Data are not available on the use of diphenhydramine hydrochloride as a nighttime sleep-aid in children under 12 years.

The basis for determining the most effective dosage regimen will be the response of the patient to medication and the condition under treatment.

In motion sickness, full dosage is recommended for prophylactic use, the first dose to be given 30 minutes before exposure to motion and similar doses before meals and upon retiring for the duration of exposure

## **STORAGE**

**Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].  
Protect from freezing and light.**

## **HOW SUPPLIED**

**Each 5 mL of Diphenhydramine Hydrochloride Oral Solution USP** (clear purple/red liquid, cinnamon/anise flavor) contains 12.5 mg diphenhydramine hydrochloride with 14% alcohol and is supplied in the following oral dosage forms:

NDC: 0121-0489-04: 118 mL (4 oz) bottle

NDC 0121-0489-05: 5 mL unit dose cup

NDC 0121-0489-00: Case contains 100 unit dose cups of 5 mL (0121-0489-05) packaged in 10 trays of 10 unit dose cups each.

NDC 0121-0978-10: 10 mL unit dose cup

NDC 0121-0978-00: Case contains 100 unit dose cups of 10 mL (0121-0978-10) packaged in 10 trays of 10 unit dose cups each.

### ***Pharmaceutical Associates, Inc.***

Greenville, SC 29605

[www.paipharma.com](http://www.paipharma.com)

R02/20

## **PRINCIPAL DISPLAY PANEL - CUP LABEL**

Delivers **10 mL**

**DIPHENHYDRAMINE HCl**

**ORAL SOLUTION USP**

**25 mg/10 mL**

**Alcohol 14%**

**FOR INSTITUTIONAL USE ONLY**

**Store at 20° to 25°C (68° to 77°F).**

**[See USP Controlled Room Temperature].**

**Rx ONLY**



**PRINCIPAL DISPLAY PANEL - OUTER PACKAGE**

NDC 71872-7242-1

Rx Only

Diphenhydramine HCl Oral Solution USP

25mg/10 mL

1 - 10 mL Unit-Dose Cup

Alcohol 14%



Rx only



(01) 0 0871872 72421 0  
(17) 000101  
(10) XXXX-XXXXXX  
(21) 7242A00000

**Diphenhydramine HCl Oral Solution USP**  
**25 mg/10 mL Unit-Dose Cup**

Qty: 1 cup      Lot# XXXX-XXXXXX      Exp: 01/01/1900

Alcohol 14%

Usual Dosage: See Insert

This unit-dose package is not child-resistant.

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

Manufactured by: Pharmaceutical Associates, Inc. Greenville, SC 29605  
Manufacturer NDC: 00121-0978-10

Repackaged  
& Distributed By:



Medical Purchasing Solutions  
Scottsdale, AZ 85260  
www.medicalpurchasingsolutions.com

## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:71872-7242(NDC:0121-0978)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCROSE</b> (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CINNAMON	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71872-7242-1	1 in 1 BAG	03/01/2021	
1		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA087513	02/10/1982	

**Labeler** - Medical Purchasing Solutions, LLC (601458529)

### Establishment

Name	Address	ID/FEI	Business Operations
Medical Purchasing Solutions, LLC		601458529	repack(71872-7242)

Revised: 4/2023

Medical Purchasing Solutions, LLC