

**DIPHENHYDRAMINE HCL ORAL SOLUTION- diphenhydramine hcl oral solution**  
**Rising Pharma Holdings, Inc.**

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**Diphenhydramine HCl Oral Solution 12.5 mg/5 mL**

***Drug Facts***

***Active ingredient per 5 mL (1 Unit Dose)***

Diphenhydramine HCl 12.5 mg

***Purpose***

Antihistamine

***Uses***

- Temporarily relieves these symptoms due to hay fever or other respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat

***Warnings***

**Do not use**

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

**Ask a doctor before use if the child has**

- a breathing problem such as chronic bronchitis
- glaucoma

**Ask a doctor or pharmacist before use if the child is** taking sedatives or tranquilizers

**When using this product**

- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

**Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

***Directions***

- take every 4 to 6 hours, or as directed by a physician
- do not take more than 6 doses in 24 hours

<b>age</b>	<b>dose</b>
Children under 2 years of age	Do not use
Children 2 to under 6 years of age	Do not use unless directed by a doctor
Children 6 to under 12 years of age	5 mL (12.5 mg) to 10 mL (25 mg)

### **Other information**

- each 5 mL contains sodium: 3 mg
- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- do not use if lid is torn or broken

**Inactive ingredients:** citric acid, flavor, FD&C red#40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose

**Questions or comments?** Call 1-844-474-7464

### **Distributed by:**

Rising Pharma Holdings, Inc.  
East Brunswick, NJ 08816

FG-35/lss.: 10/2023

### **NDC Information -**

**12.5 mg/5 mL**

**Each 5 mL of Diphenhydramine HCl Oral Solution contains Diphenhydramine HCl 12.5 mg and is supplied in the following oral dosage forms:**

**NDC 57237-317-05: 5 mL unit dose cup**

**NDC 57237-317-51: 100 x 5 mL Unit-Dose Cups**

### **PRINCIPAL DISPLAY PANEL**

**12.5 mg/5 mL**

**Case Label NDC 57237-317-51**

**Diphenhydramine HCl  
Oral Solution  
12.5 mg/5 mL**

**Antihistamine**

- Alcohol Free
- Sugar Free
- Cherry Flavor

**USUAL DOSAGE:** See attached Drug Facts

**FOR INSTITUTIONAL USE  
ONLY**

**100 x 5 mL Unit-Dose Cups**

<b>Drug Facts</b>									
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<b>Distributed by:</b> Rising Pharma Holdings, Inc. East Brunswick, NJ 08816 FG-35/Iss.: 10/2023	 N 3 57237 31751 8								

NDC 57237-317-51



**Diphenhydramine HCl  
Oral Solution  
12.5 mg/5 mL**

**100 x 5 mL Unit-Dose Cups**



LOT#

Exp. Date:

Unvarnished Area

**Lid Label NDC 57237-317-05**

Delivers 5 mL

# Diphenhydramine HCl

## Oral Solution

### 12.5 mg/5 mL

FOR INSTITUTIONAL USE ONLY

Exp: YYYY/MM Lot#: XXXXXX

Dist. By: Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Iss. 12/2023 FG-35 SEE LABEL



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### DIPHENHYDRAMINE HCL ORAL SOLUTION

diphenhydramine hcl oral solution

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-317
Route of Administration	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

#### Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-317-51	100 in 1 BOX, UNIT-DOSE	12/15/2023	
1	NDC:57237-317-05	5 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
OTC Monograph Drug	M009.50	12/15/2023	

**Labeler** - Rising Pharma Holdings, Inc. (116880195)

Revised: 7/2025

Rising Pharma Holdings, Inc.