

# **DIPHENHYDRAMINE HCL- diphenhydramine hcl solution**

## **Bellevue Biosciences**

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### **Diphenhydramine HCL**

Directions: Take every 4-6 hours, or as directed by doctor. \* Do NOT exceed the recommended dose

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Age	Dose
Adults and Children 12 years of age and over	take 10 to 20 mL (2 to 4 tsp), not to exceed 300 mg in 24 hours
Children 6 to under 12 years of age	take 5 to 10 mL (1 to 2 tsp) not to exceed 150 mg in 24 hours
Children under 6 years of age	Consult a doctor

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#### Warnings:

Do not use: ■ with any other product containing diphenhydramine, even one used on skin ■ to make a child sleepy

Ask a doctor before use if you have: ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to the enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product: ■ excitability might occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness effect ■ be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

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

Inactive Ingredients: Citric Acid, Flavor, Methylparaben, Monoammonium

Glycyrrhizinate, Potassium Citrate, Propylene Glycol,  
Propylparaben, Purified Water, Sorbitol, Sucralose

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

Keep out of reach of children.

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

Purpose: Antihistamine

Active Ingredient (in each 5 mL tsp)

Diphenhydramine HCL, 12.5 mg

## **Drug Facts**



**NDC 84447-103-01**  
**Diphenhydramine HCl**  
**12.5 mg / 5 ml**  
**Bulk Label**

**Lot:**  
**Mfg:**

**BULK SHIPMENT**  
**PLEASE HANDLE CAREFULLY**

**Contains:**

12.5mg Diphenhydramine HCL per 5 ml; Inactive  
 Ingredients: Citric Acid, Flavor, Methylparaben,  
 Monoammonium Glycyrhizinate, Potassium Citrate,  
 Propylene Glycol, Propylparaben, Purified Water, Sorbitol,  
 Sucralose

**\*\*Sugar, Alcohol, Gluten and Dye Free\*\***

**CAUTION:**  
**FOR REPACKAGING ONLY**  
 Store at controlled room temperature 15°-30°C (59°- 86°F)

**BELLEVIEW**  
**BIOSCIENCE**  
 Manufactured by:  
 Belleview Biosciences LLC.  
 Brooksville, FL 34604

Gross wt: _____
Tare wt: _____
Net wt: _____
Drum: ____ of ____

**DIPHENHYDRAMINE HCL**

diphenhydramine hcl solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84447-103
<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	12.5 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>		<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:84447-103-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2024	
2	NDC:84447-103-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2024	
3	NDC:84447-103-01	200000 mL in 1 DRUM; Type 0: Not a Combination Product	07/20/2024	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/20/2024	

**Labeler -** Belleview Biosciences (131968803)

Revised: 7/2024

Belleview Biosciences