

DIPHENHYDRAMINE HCL- diphenhydramine hcl solution

Bellevue Biosciences

Diphenhydramine HCL

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

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

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 Glycyrrhizinate, 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:
Bellevue Biosciences LLC.
Brooksville, FL 34604

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

DIPHENHYDRAMINE HCL

diphenhydramine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84447-103
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
WATER (UNII: 059QF0KO0R)	
NONCRYSTALLIZING SORBITOL SOLUTION (UNII: 9E0S3UM200)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CITRIC ACID (UNII: 2968PHW8QP)	

POTASSIUM CITRATE (UNII: EE90ONI6FF)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
AMMONIUM GLYCYRRHIZINATE TRIHYDRATE (UNII: 78NEL3149I)	
CHERRY (UNII: BUC5I9595W)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

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: 6/2025

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