

DIPHENHYDRAMINE HCL- diphenhydramine hydrochloride solution
American Health Packaging

Diphenhydramine Hydrochloride Oral Solution USP
Drug Facts

Active ingredient (in each 5 mL)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

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

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

Directions:

- find right dose on chart below
- mL = milliliter
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 doses in 24 hours

Age (yr)	Dose (mL)
children under 2 years	do not use
children 2 to 5 years	do not use unless directed by a doctor
children 6 to 11 years	5 mL to 10 mL

Other information

- each 5 mL contains: sodium 10 mg
- store between 20-25°C (68-77°F). Protect from light. Store in outer carton until contents used.

Diphenhydramine HCl Oral Solution, USP is a clear, cherry flavored liquid supplied in the following:

5 mL unit dose cups: 100 cups (10 x 10) NDC 60687-829-86

Inactive ingredients:

citric acid anhydrous, glycerin, flavoring, purified water, saccharin sodium, sodium benzoate, sodium carboxymethylcellulose, sodium citrate, sorbitol.

Questions or comments?

Call 1-800-845-8210

DO NOT USE IF SEAL IS BROKEN.

Distributed by:

American Health Packaging

Columbus, OH 43217

R02/24

Principal Display Panel - Label

100 Count Case NDC 60687-829-86
Cup NDC 60687-829-40

**Diphenhydramine Hydrochloride
Oral Solution USP**

12.5 mg/5 mL

Antihistamine/Allergy
Alcohol Free/Dye Free/Sugar Free

Usual Dosage: See attached Drug Facts

Store at 20° to 25°C (68° to 77°F)

For Institutional Use Only

10 x 5 mL Unit-Dose Cups

T0865C050224

R02/24

100 Count Case NDC 60687-829-86
Cup NDC 60687-829-40

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Oral Solution USP**

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R02/24

Principal Display Panel - Cup - 12.5 mg/5 mL



NDC 60687- **829**-40

**Diphenhydramine
Hydrochloride
Oral Solution USP**

12.5 mg/5 mL

Antihistamine/Allergy

Alcohol Free/Dye Free/Sugar Free

Delivers 5 mL

Sodium Content: 10 mg/5 mL

See package Drug Facts insert for full
prescribing information and storage.

For Institutional Use Only.

American Health Packaging
Columbus, OH 43217

A0865C050224

DIPHENHYDRAMINE HCL

diphenhydramine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60687-829
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white (CLEAR)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60687-829-86	10 in 1 CASE	08/04/2024	
1	NDC:60687-829-46	10 in 1 TRAY		
1	NDC:60687-829-40	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	M012	08/04/2024	

Labeler - American Health Packaging (929561009)