DIPHENHYDRAMINE HCL- diphenhydramine hydrochloride solution
Major Pharmaceuticals

Diphenyhydramine HCl 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 no 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° to 25°C (68° to 77°F).

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

NDC 0904-7560-41: 5 mL unit dose cup, in a tray of 10 cups.
NDC 0904-7559-66: 10 mL unit dose cup, in a tray of 10 cups.

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

R02/25

Distributed by:

MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268

PRINCIPAL DISPLAY PANEL

Delivers 5 mL

NDC0904-7560-41

Diphenydramine HCl Oral Solution USP

12.5 mg/5 mL

PRINCIPAL DISPLAY PANEL

Delivers 10 mL

NDC0904-7559-66

Diphenydramine HCl Oral Solution USP

25 mg/10 mL

DIPHENHYDRAMINE HCL

diphenhydramine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-7560(NDC:0121-0865)
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 (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:0904-7560-70	10 in 1 CASE	08/01/2025	
1		10 in 1 TRAY		
1	NDC:0904-7560-41	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	07/15/2025	

DIPHENHYDRAMINE HCL

diphenhydramine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-7559(NDC:0121-1730)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 10 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 (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:0904-7559-72	10 in 1 CASE	08/01/2025	
1		10 in 1 TRAY		
1	NDC:0904-7559-66	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
OTC Monograph Drug	M012	07/15/2025	

Labeler - Major Pharmaceuticals (191427277)

Revised: 8/2025 Major Pharmaceuticals