DIPHENHYDRAMINE HCL- diphenhydramine hydrochloride solution
PAI Holdings, LLC

Diphenydramine 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 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

Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

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.

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

PRINCIPAL DISPLAY PANEL

Delivers 5 mL

NDC 0121-0865-05

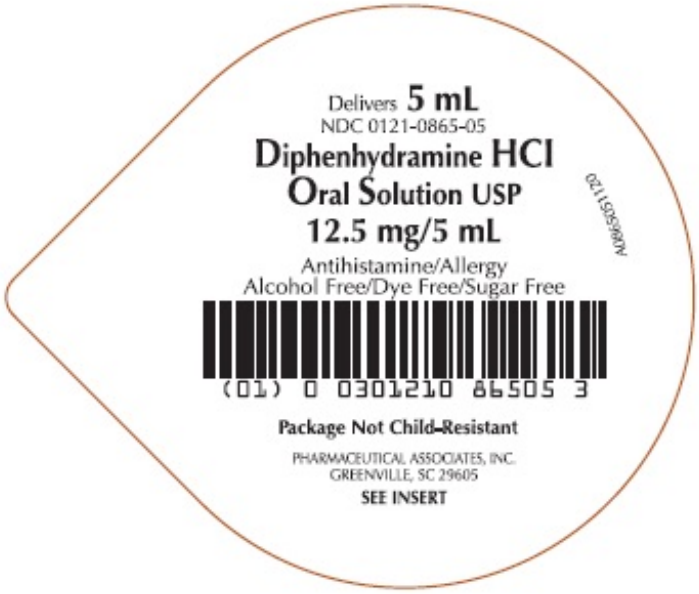
Diphenydramine HCl Oral Solution USP

12.5 mg/5 mL

Antihistamine/Allergy

Alcohol Free/Dye Free/Sugar Free

Package Not Child-Resistant



PRINCIPAL DISPLAY PANEL

Delivers 10 mL

NDC 0121-1730-10

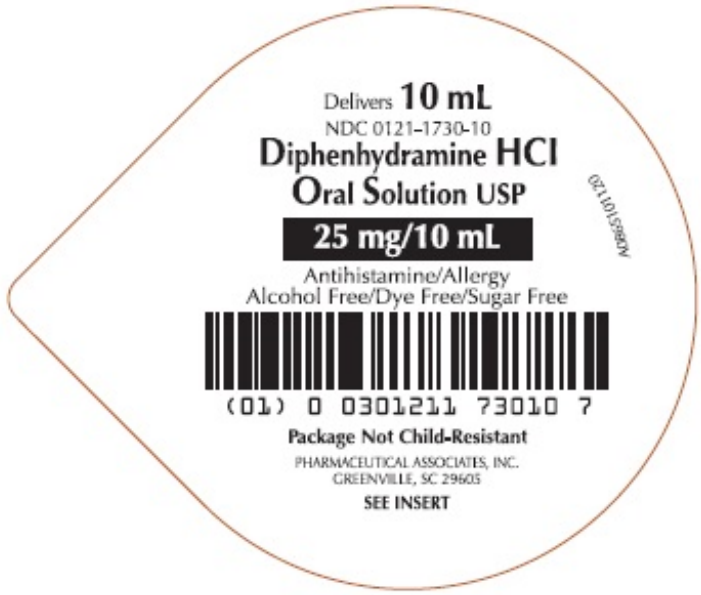
Diphenydramine HCl Oral Solution USP

25 mg/10 mL

Antihistamine/Allergy

Alcohol Free/Dye Free/Sugar Free

Package Not Child-Resistant



DIPHENHYDRAMINE HCL

diphenhydramine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:0121-0865-00	10 in 1 CASE	06/18/2020	
1		10 in 1 TRAY		
1	NDC:0121-0865-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-0865-30	3 in 1 CASE	06/18/2020	
2		10 in 1 TRAY		
2	NDC:0121-0865-05	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	M012	06/18/2020	

DIPHENHYDRAMINE HCL

diphenhydramine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:0121-1730-00	10 in 1 CASE	06/18/2020	
1		10 in 1 TRAY		
1	NDC:0121-1730-10	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-1730-30	3 in 1 CASE	06/18/2020	

2		10 in 1 TRAY		
2	NDC:0121-1730-10	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	06/18/2020	

Labeler - PAI Holdings, LLC (044940096)

Establishment

Name	Address	ID/FEI	Business Operations
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma		097630693	manufacture(0121-0865, 0121-1730)

Revised: 1/2024 PAI Holdings, LLC