

SILADRYL ALLERGY MEDICINE- diphenhydramine hydrochloride liquid
American Health Packaging

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Diphenhydramine Hydrochloride
Liquid Antihistamine
8426769/1121F

Active ingredient

(in each 10 mL cup)

Diphenhydramine HCl 25 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 you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- a sodium restricted diet

Ask a doctor or pharmacist before use

if you are taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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 right away (1-800-222-1222).

Directions

- find right dose on chart below
- take every 4 to 6 hours
- do not take more than 6 doses in any 24-hour period

adults and children 12 years and over	1 cup (10 mL) to 2 cups (20 mL)
children 6 to under 12 years	1/2 cup (5 mL) to 1 cup (10 mL)
children under 6 years	DO NOT USE

Other information

- **Each 10 mL cup contains:** Sodium 28 mg.
- Store between 20° to 25°C (68° to 77°F).
- Protect from light.
- **DO NOT USE IF SEAL IS BROKEN.**
- This drug product is supplied in 10 mL unit dose cups as:
 - 30 cups (3 x 10) NDC 60687-267-08
 - 100 cups (10 x 10) NDC 60687-267-56

Inactive ingredients

citric acid, D&C red no. 33, FD&C red no. 40, black cherry flavor, methylparaben, propylene glycol, propylparaben, saccharin sodium, sodium citrate, sorbitol, water.

PACKAGING INFORMATION

American Health Packaging unit dose cups contain drug product Siladryl Allergy (Diphenhydramine Hydrochloride) from Silarx Pharmaceuticals, Inc. as follows:
(25 mg per 10 mL / 30 UD) NDC 60687-267-08 packaged from NDC 54838-135
(25 mg per 10 mL / 100 UD) NDC 60687-267-56 packaged from NDC 54838-135

Distributed by:
American Health Packaging
Columbus, OH 43217

8426769/1121F

Principal Display Panel

**Diphenhydramine
Hydrochloride
Liquid
Antihistamine**

• Sugar Free • Alcohol Free

FOR INSTITUTIONAL USE ONLY

Store between
20° and 25°C (68° and 77°F).
Protect from light.

8426769/1121F

**Diphenhydramine
Hydrochloride
Liquid
Antihistamine**

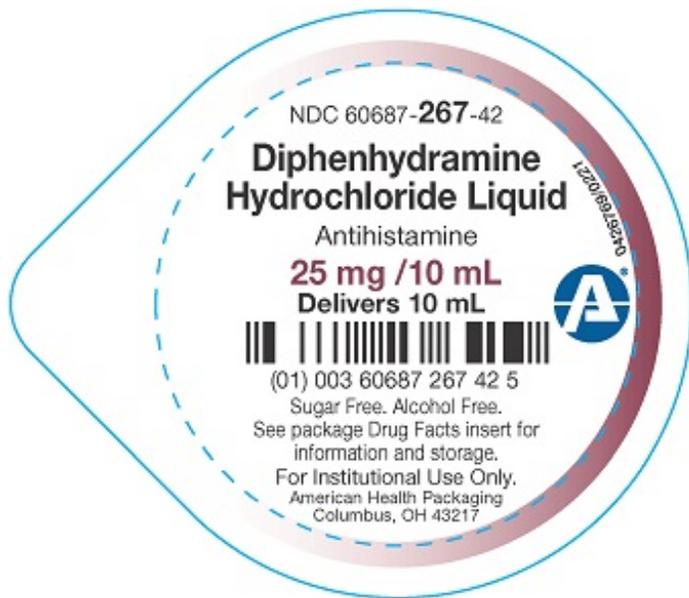
• Sugar Free • Alcohol Free

FOR INSTITUTIONAL USE ONLY

Store between
20° and 25°C (68° and 77°F).
Protect from light.

8426769/1121F

Principal Display Panel - Cup - 25 mg per 10 mL/10 mL



NDC 60687- **267**-42

**Diphenhydramine
Hydrochloride Liquid**

Antihistamine

25 mg / 10 mL

Delivers 10 mL

Sugar Free. Alcohol Free.

See package Drug Facts insert for
information and storage.

For Institutional Use Only.

American Health Packaging
Columbus, OH 43217

0426769/0221

SILADRYL ALLERGY MEDICINE

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60687-267(NDC:54838-135)
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)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (black cherry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60687-267-56	10 in 1 CASE	06/05/2020	11/30/2024
1	NDC:60687-267-48	10 in 1 TRAY		
1	NDC:60687-267-42	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:60687-267-08	3 in 1 CASE	03/01/2022	10/31/2024
2	NDC:60687-267-48	10 in 1 TRAY		
2	NDC:60687-267-42	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 final	part341	06/05/2020	11/30/2024

Labeler - American Health Packaging (929561009)

Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(60687-267)

