

SILADRYL ALLERGY MEDICINE - diphenhydramine hydrochloride liquid
Silarx Pharmaceuticals, Inc

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.

Siladryl Allergy Liquid Medicine

Active Ingredient: Diphenhydramine HCl 12.5 mg (in each 5 mL (teaspoonful)(TSP))

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

- repeat dose every 4 to 6 hours
- do not take more than 6 doses in any 24-hour period
- Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

adults and children 12 years and over	2 to 4 teaspoonfuls (TSP)
children 6 to under 12 years	1 to 2 teaspoonfuls (TSP)
children under 6 years	DO NOT USE

Other information

Each 5 mL (1 TSP) contains: Sodium 14 mg. Store at room temperature 20°-25°C (68°-77°F).

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.

Questions

888-974-5279

Manufactured by:

Silarx Pharmaceuticals, Inc.
1033 Stoneleigh Ave
Carmel, NY 10512
USA



NDC 54838-135-40

Siladryl

ALLERGY

Liquid Medication

Diphenhydramine Hydrochloride

Antihistamine

■ Sugar Free ■ Alcohol Free

DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING

118 mL (4 fl oz)

Drug Facts

Active ingredient (in each 5 mL (teaspoonful) (TSP)) Purpose
Diphenhydramine HCl 12.5 mg 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 ■ 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 ■ **and** night dose on chart below ■ take every 4 to 6 hours ■ do not take more than 6 doses in 24 hours ■ Attention: use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.


adults and children 12 years and over	2 to 4 teaspoonfuls (TSP)	DO NOT USE
children 6 to under 12 years	1 to 2 teaspoonfuls (TSP)	

Other information each 5 mL (1 TSP) contains: sodium 14 mg ■ Store between 20-25°C (68-77°F) ■ Protect from light.

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.

Manufactured by: Silarx Pharmaceuticals, Inc. Carmel, NY 10512
Rev. 07/13
Questions © 888-974-5279

Control # **54838-135-40** Exp. Date



SILADRYL ALLERGY MEDICINE

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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)	
methylparaben (UNII: A2I8C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
saccharin sodium dihydrate (UNII: SB8ZUX40TY)	
sodium citrate (UNII: 1Q73Q2JULR)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0KO0R)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
FD&C red no. 40 (UNII: WZB9127XOA)	

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:54838-135-40	118 mL in 1 BOTTLE		
2	NDC:54838-135-70	237 mL in 1 BOTTLE		
3	NDC:54838-135-80	473 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/1997	

Labeler - Silarx Pharmaceuticals, Inc (161630033)

Revised: 6/2014

Silarx Pharmaceuticals, Inc