SILADRYL ALLERGY MEDICINE- diphenhydramine hydrochloride liquid
NuCare 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

- 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

1-844-834-0530

Manufactured by:

Silarx Pharmaceuticals, Inc.
Carmel, NY 10512

10-1043 Rev. 04/18

SILADRYL ALLERGY MEDICINE

diphenhydramine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66267-977(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 (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:66267-977-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2018	

Marketing Information

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

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(66267-977)

Revised: 1/2022 NuCare Pharmaceuticals,Inc.