DIPHENHYDRAMINE HYDROCHLORIDE - diphenhydramine hydrochloride solution
CVS Pharmacy, 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.

Diphenhydramine HCl Oral Solution

Drug Facts

Active ingredient [in each 20 mL]

Diphenhydramine HCl, USP 50 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - sneezing
  - itchy, watery eyes
  - runny nose
  - 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

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

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

Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 doses in 24 hours
- not to exceed 300 mg in 24 hours
- mL = milliliter

Age (yr)	Dose (mL)
Adult and children 12 years and older	10 mL to 20 mL
Children under 12 years	Consult a doctor

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

Other information

- each 20 mL contains: **sodium 56 mg**
- store between 20-25°C (68-77°F). Protect from light. Store in outer carton until contents used
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, flavor, high fructose corn syrup, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucralose

Questions or comments?

1-855-274-4122

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895

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Product of India
V-31735

CVS® Quality
Money Back Guarantee

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 4 FL OZ (118 mL Bottle)

CVS
HealthTM

NDC 59779-973-24

MAXIMUM STRENGTH
Adult
Allergy
Relief
LIQUID MEDICATION
DIPHENHYDRAMINE HCl
50 mg/20 mL
ORAL SOLUTION
Antihistamine

Relieves:

- **Sneezing**
- **Runny nose**
- **Itchy, watery eyes**
- **Itchy throat**

DYE FREE

Grape Flavor
Alcohol free
Actual Bottle Size on Side Panel

4 FL OZ (118 mL)

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59779-973
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GRAPE (UNII: 6X543N684K)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	YELLOW (Colorless to Pale Yellow)	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-973-24	1 in 1 CARTON	11/02/2015	
1		118 mL in 1 BOTTLE; 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	11/02/2015	

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations

Aurohealth LLC		078728447	MANUFACTURE(59779-973)