ALLERGY RELIEF- diphenhydramine hcl liquid
LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION

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.

Active ingredient (in each 5 mL teaspoonful)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

- Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
- runny nose
- itchy nose or throat
- sneezing
- itchy, watery eyes
- Temporarily relieves these symptoms due to the common cold:
- runny nose
- sneezing

Warnings

Do not use

- with any other product conatining diphenhydramine, including one used on the skin
- to make a child sleepy

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

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

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.

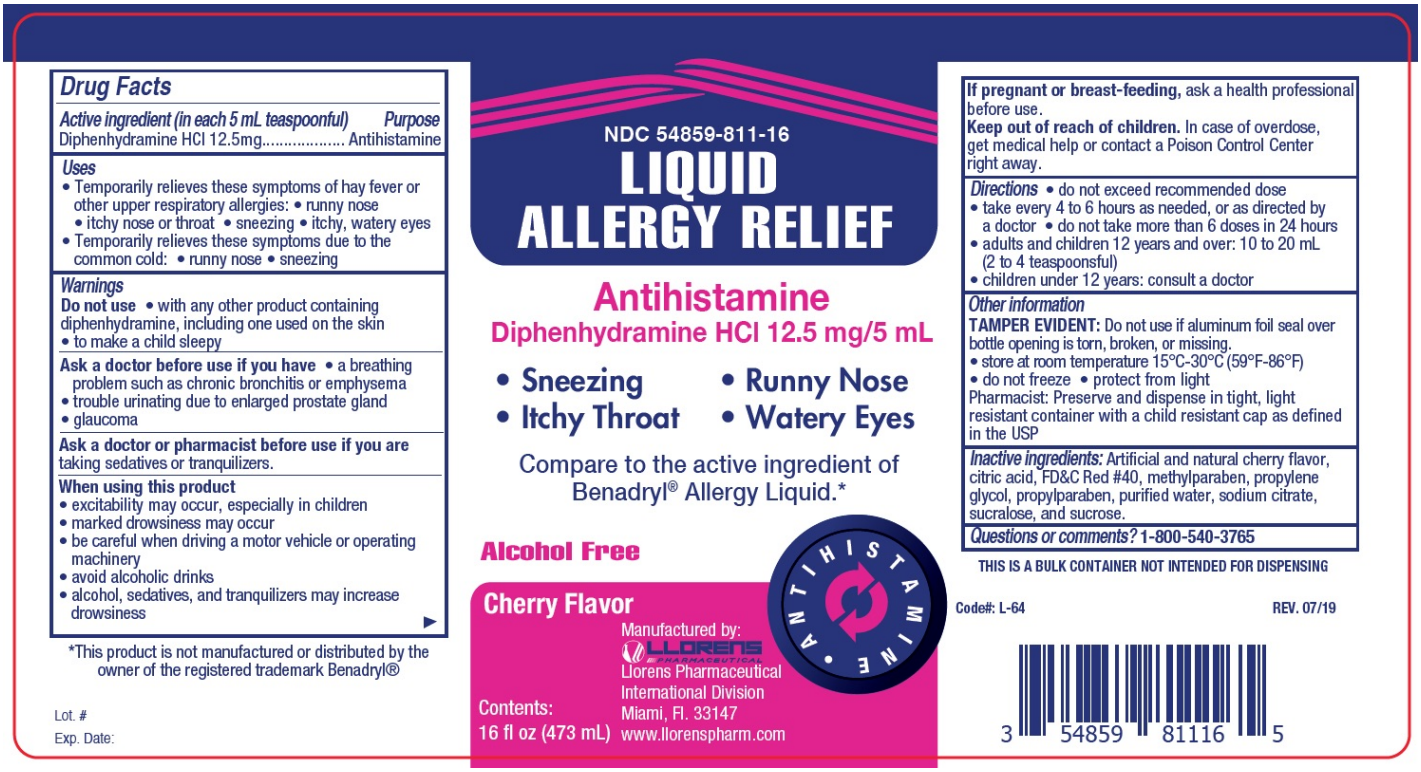
Directions

- do not exceed recommended dose
- take every 4 to 6 hours as needed, or as directed by a doctor
- do not take more than 6 doses in 24 hours
- adults and children 12 years and over: 10 to 20 mL (2 to 4 teaspoonful)

- children under 12 years: consult a doctor

Inactive ingredients: Artificial and natural cherry flavor, citric acid, FD&C #40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose and sucrose.

Questions or comments? 1-800-540-3765



ALLERGY RELIEF

diphenhydramine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-811
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-811-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2019	

Labeler - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Registrant - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Establishment

Name	Address	ID/FEI	Business Operations
LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION		037342305	manufacture(54859-811)

Revised: 10/2019 LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION