

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 containing 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

NDC 54859-811-16

 **Llorens Pharmaceutical**

**LIQUID
ALLERGY RELIEF**
DIPHENHYDRAMINE HCL 12.5 MG/5 ML

✓ Compare to the active ingredient of
Benadryl® Allergy Liquid.*

✓ Sneezing
✓ Itchy Throat
✓ Runny Nose
✓ Watery Eyes

**CHERRY
FLAVOR**

16 FL OZ (473 mL)

| Drug Facts | |
|--|---------------------------------|
| Active Ingredient (in each 5 mL teaspoonful) Diphenhydramine HCl 12.5mg | Purpose Antihistamine |
| USES Temporarily relieves these symptoms due to 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 containing 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 a 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. | |

| Drug Facts (continued) | |
|--|--|
| 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 | |
| OTHER INFORMATION TAMPER EVIDENT: Do not use if aluminum foil seal over bottle opening is torn, broken, or missing. • store at room temperature 15°C-30°C (59°F-86°F) • do not freeze • protect from light Pharmacist: Preserve and dispense in tight, light resistant container with child resistant cap as defined in the USP Inactive ingredients: Artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose, and sucrose. | |
| *This product is not manufactured or distributed by the owner of the registered trademark Benadryl® | |
| Questions or comments? 1-800-595-5598 THIS IS A BULK CONTAINER NOT INTENDED FOR RETAIL Manufactured by: Code #: L-64 Rev.: 05/22 Llorens Pharmaceutical International Division, Inc. Miami, FL 33147 WWW.LLORENSPHARM.COM | |
| Lot #: Exp Date: |  3 54859 81116 5 |

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: 7/2022

LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION