

DIPHENHYDRAMINE ORAL LIQUID- diphenhydramine hydrochloride liquid
Rising Pharma Holdings, Inc.

Drug Facts

Active ingredient in each 5 mL (in one teaspoonful)

Diphenhydramine HCl, 12.5 mg

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

temporarily relieves these symptoms due to the common cold:

- runny nose
- sneezing

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.

Directions

- take every 4-6 hours
- Do not use more than 6 dose in 24 hours

adults and children 12 years of age and over	2 to 4 teaspoonfuls (25 to 50 mg)
children 6 to under 12 years of age	1 to 2 teaspoonfuls (12.5 to 25 mg)
children under 6 years	ask a doctor

Other information

- store at room temperature 15° - 30°C (59° - 86°F)
- protect from freezing
- protect from light
- each teaspoon (5 mL) contains: sodium 8 mg

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING.

Inactive ingredients

cherry flavor, citric acid, D & C Red #33, FD & C Red #40, flavor, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, sucrose, water.

Questions or comments?

1-844-474-7464

PRINCIPAL DISPLAY PANEL

Rising Health, LLC

NDC 57237-305-12

Diphenhydramine Hcl 12.5 mg/5 mL Oral Solution

4 fl oz (118 mL)



NDC 57237-305-12

Compare to the active ingredient
in Benadryl® Liquid*

Diphenhydramine HCl

12.5 mg/5 mL
Oral Solution

**Children's Allergy
Relief****Antihistamine**

- Alcohol Free
- Relieves:
 - Sneezing
 - Runny Nose
 - Itchy, Watery Eyes
 - Itchy Throat

**Cherry
Flavor****4 fl oz (118 mL)**

Drug Facts

Active ingredient in each 5 mL (in one teaspoonful)
Diphenhydramine HCl 12.5 mg.....Antihistamine**Purpose****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 ■ temporarily relieves these symptoms due to the common cold: ■ runny nose ■ sneezing**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. ▶

Drug Facts (continued)

Directions ■ take every 4-6 hours
■ Do not take more than 6 dose in 24 hours.adults and children 12
years of age and over2 to 4 teaspoonfuls
(25 to 50 mg)children 6 to under 12
years of age1 to 2 teaspoonfuls
(12.5 to 25 mg)

children under 6 years

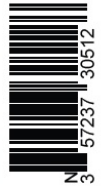
ask a doctor

Other information ■ store at room temperature 15°-30° C (59°-86°F) ■ protect from freezing ■ protect from light ■ each teaspoon (5mL) contains: sodium 8 mg**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING.****Inactive ingredients:** cherry flavor, citric acid, D&C Red #33, FD&C Red #40, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, sucrose, water.**Questions or comments?**
1-844-474-7464

*This product is not manufactured or distributed by the owner of the registered trademark of Benadryl®

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Issued: 08/22

Lot/Exp
Date**SPOT UV**

DIPHENHYDRAMINE ORAL LIQUID

diphenhydramine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-305
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)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbitol (UNII: 506T60A25R)	
Sucrose (UNII: C151H8M554)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color	PINK (dark pink to pink)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-305-12	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/19/2022	
2	NDC:57237-305-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/19/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M009.50	12/19/2022	

Labeler - Rising Pharma Holdings, Inc. (116880195)**Establishment**

Name	Address	ID/FEI	Business Operations
Invahealth Inc.		116840615	manufacture(57237-305) , pack(57237-305) , label(57237-305) , analysis(57237-305)

Revised: 10/2024

Rising Pharma Holdings, Inc.