

DIPHENHYDRAMINE ORAL LIQUID- diphenhydramine hydrochloride liquid **Rising Health, LLC**

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.

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)

Rising HEALTH 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



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)

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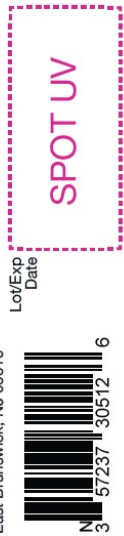
Inactive ingredients: cherry flavor, citric acid, D&C Red #33, FD&C Red #40, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, sucrose, water.

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

Lot/Exp Date
Issued: 08/22



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 FINAL	part341	12/19/2022	

Labeler - Rising Health, LLC (080500961)

Establishment

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

Revised: 12/2022

Rising Health, LLC