

DIPHENHYDRAMINE HCL ORAL SOLUTION- diphenhydramine hcl oral solution
Rising Pharma Holdings, Inc.

Diphenhydramine HCl Oral Solution 12.5 mg/5 mL

Drug Facts

Active ingredient per 5 mL (1 Unit Dose)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

- Temporarily relieves these symptoms due to hay fever or other respiratory allergies:
 - runny nose
 - sneezing
 - itchy, watery eyes
 - 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 the child has

- a breathing problem such as chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Directions

- take every 4 to 6 hours, or as directed by a physician
- do not take more than 6 doses in 24 hours

age	dose
Children under 2 years of age	Do not use
Children 2 to under 6 years of age	Do not use unless directed by a doctor
Children 6 to under 12 years of age	5 mL (12.5 mg) to 10 mL (25 mg)

Other information

- each 5 mL contains sodium: 3 mg
- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- do not use if lid is torn or broken

Inactive ingredients: citric acid, flavor, FD&C red#40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose

Questions or comments? Call 1-844-474-7464

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

FG-35/lss.: 10/2023

NDC Information -

12.5 mg/5 mL

Each 5 mL of Diphenhydramine HCl Oral Solution contains Diphenhydramine HCl 12.5 mg and is supplied in the following oral dosage forms:

NDC 57237-317-05: 5 mL unit dose cup

NDC 57237-317-51: 100 x 5 mL Unit-Dose Cups

PRINCIPAL DISPLAY PANEL

12.5 mg/5 mL

Case Label NDC 57237-317-51

Diphenhydramine HCl
Oral Solution
12.5 mg/5 mL

Antihistamine

- Alcohol Free
- Sugar Free
- Cherry Flavor

USUAL DOSAGE: See attached Drug Facts

FOR INSTITUTIONAL USE ONLY

100 x 5 mL Unit-Dose Cups

Drug Facts

Active Ingredient per 5 mL (1 Unit Dose)
Diphenhydramine HCl 12.5 mg. **Purpose**
Antihistamine

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NDC 57237-317-51



Diphenhydramine HCl
Oral Solution
12.5 mg/5 mL

100 x 5 mL Unit-Dose Cups



LOT#

Exp. Date:

Unvarnished Area

Lid Label NDC 57237-317-05

Delivers 5 mL

Diphenhydramine HCl

Oral Solution

12.5 mg/5 mL

FOR INSTITUTIONAL USE ONLY

Exp: YYYY/MM Lot#: XXXXXX

Dist. By: Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816

Iss. 12/2023 FG-35 SEE LABEL



5723731705

L1



DIPHENHYDRAMINE HCL ORAL SOLUTION

diphenhydramine hcl oral solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-317
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-317-51	100 in 1 BOX, UNIT-DOSE	12/15/2023	
1	NDC:57237-317-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	12/15/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - Lohxa (079872715)

Establishment

Name	Address	ID/FEI	Business Operations
Lohxa		079872715	pack(57237-317)

Establishment

Name	Address	ID/FEI	Business Operations
Ultrum Labs, LLC		060934179	manufacture(57237-317) , analysis(57237-317)