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

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## Diphenhydramine HCl Oral Solution 25 mg/10 mL

## Drug Facts

## Active ingredient per 10 mL (1 Unit Dose)

Diphenhydramine HCl 25 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 you have

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

# 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 traquilizers 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 healthcare professional before use

**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
Adults and children over 12 years of age	10 mL (25 mg) to 20 mL (50 mg)
Children 6 to under 12 years of age	10 mL (25 mg)
Children under 6 years of age	Do not use

## Other information

- each 10 mL contains sodium: 6 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-36/lss.:10/2023

## **NDC Information -**

25 mg/10 mL

Each 10 mL of Diphenhydramine HCI Oral Solution contains Diphenhydramine HCI 25 mg and is supplied in the following oral dosage forms:

NDC 57237-318-01: 10 mL unit dose cup

NDC 57237-318-11: 100 x 10 mL Unit-Dose Cups

## PRINCIPAL DISPLAY PANEL

25 mg/10 mL

Case Label NDC 57237-318-11

Rising' NDC 57237-318-11					
Diphenhydramine HCI Oral Solution	Purpose Itadia Poison Control Center	USF Controlled Hoom Temperature   FD&C red#40, methylparaben, propylene giycol, propylparaben, purfiled 74-7464 3 57237 31811 9			
25 mg/10 mL	e or throse e or chrose dose (60 mg)	572			
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<ul> <li>Cherry Flavor</li> <li>USUAL DOSAGE: See attached Drug Facts</li> <li>FOR INSTITUTIONAL USE</li> </ul>	Drugg Facts     Purpose       Activity instruction     Activity and the tot in the form (1 Unit Dose)     Purpose       Activity instruction     Activity and the tot in the form     Activity and the tot in the form       Uses     Temporarily problem the HCI 25 mg     Activity and the tot on the form     Activity and the tot in the form       Uses     Temporarily problem such as a choic bronching of the nose or throat     Activity and the form     Activity and the form       Use as a choic backer of the form and as choic bronching of the nose or throat     Interest total     Interest total       Use as a choic backer of the form and as a choic bronching of the nose or throat     Interest total     Interest total       Use as a choic backer of the form and a choic bronching of the nose or throat     Interest total     Interest total       As a doctor backer of the form and a schore bronching of the nose or tranquitzers     Interest total     Interest total       As a doctor or pharmacist before use if you have     Interest total     Interest total     Interest total       As a doctor or pharmacist before use if you have     Interest total     Interest total     Interest total       As a doctor or pharmacist before use if you have     Interest total     Interest total     Interest total       As a doctor or pharmacist before use if you have     Interest total     Interest total     Interest total       As a doctor or pharmacist before use if y	25°C (aff to 71°C). [See life finance broken lifents: catric acid, flavor, tatele, and sucratose omments? Call 1-844-4 Holdings, Inc. NJ 08816 023			
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NDC 57237-318-11	Diphenhydramine HCl Oral Solution	<b>Rising</b> ®			
N 3 57237 31811 9	25 mg/10 mL         LOT           100 x 10 mL Unit-Dose Cups         Exp. Date	Unvarnished Area			

Lid Label NDC 57237-318-01



DIPHENHYDRAMINE diphenhydramine hcl oral solu		UTION					
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:57237-318			
Route of Administration	ORAL						
Active Ingredient/Active Moiety							
Ingredient Name Basis of Stree					Strength		
DIPHENHYDRAMINE HYDROCHLO (DIPHENHYDRAMINE - UNII:8GTS82S			DIPHENHYDRAMINE HYDROCHLORIDE	E	25 mg in 10 mL		
Inactive Ingredients							
	Ingredient Name			St	rength		
CITRIC ACID MONOHYDRATE (UI	NII: 2968PHW8QP)						
FD&C RED NO. 40 (UNII: WZB912	7XOA)						

MI	ETHYLPARABEN	(UNII: A218C7F	1I9T)					
PF	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)							
PF	OPYLPARABEN	(UNII: Z8IX2SC	C10H)					
sc	DIUM CITRATE	(UNII: 1Q73Q2	JULR)					
รเ	ICRALOSE (UNII:	: 96K6UQ3ZD4)	)					
WATER (UNII: 059QF0KO0R)								
P	roduct Char	acteristics	i					
Color red			red	Score				
Shape			Size	Size				
Flavor		CHERRY	Imprint C	Imprint Code				
Contains								
Pa	Packaging							
#	Item Code	P	Package Description		Marketing Start Date	Marketing End Date		
1	NDC:57237- 318-11	100 in 1 BOX,	in 1 BOX, UNIT-DOSE		12/15/2023			
1	NDC:57237- 318-01	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product						
Marketing Information								
	Marketing Category	Applica	ation Number or Mon Citation	ograph	Marketing Start Date	Marketing End Date		
ОТ	C Monograph Dr	ug M			12/15/2023			

Labeler - Rising Pharma Holdings, Inc. (116880195)

Revised: 1/2024

Rising Pharma Holdings, Inc.