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

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/Iss.:10/2023

NDC Information -

25 mg/10 mL

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

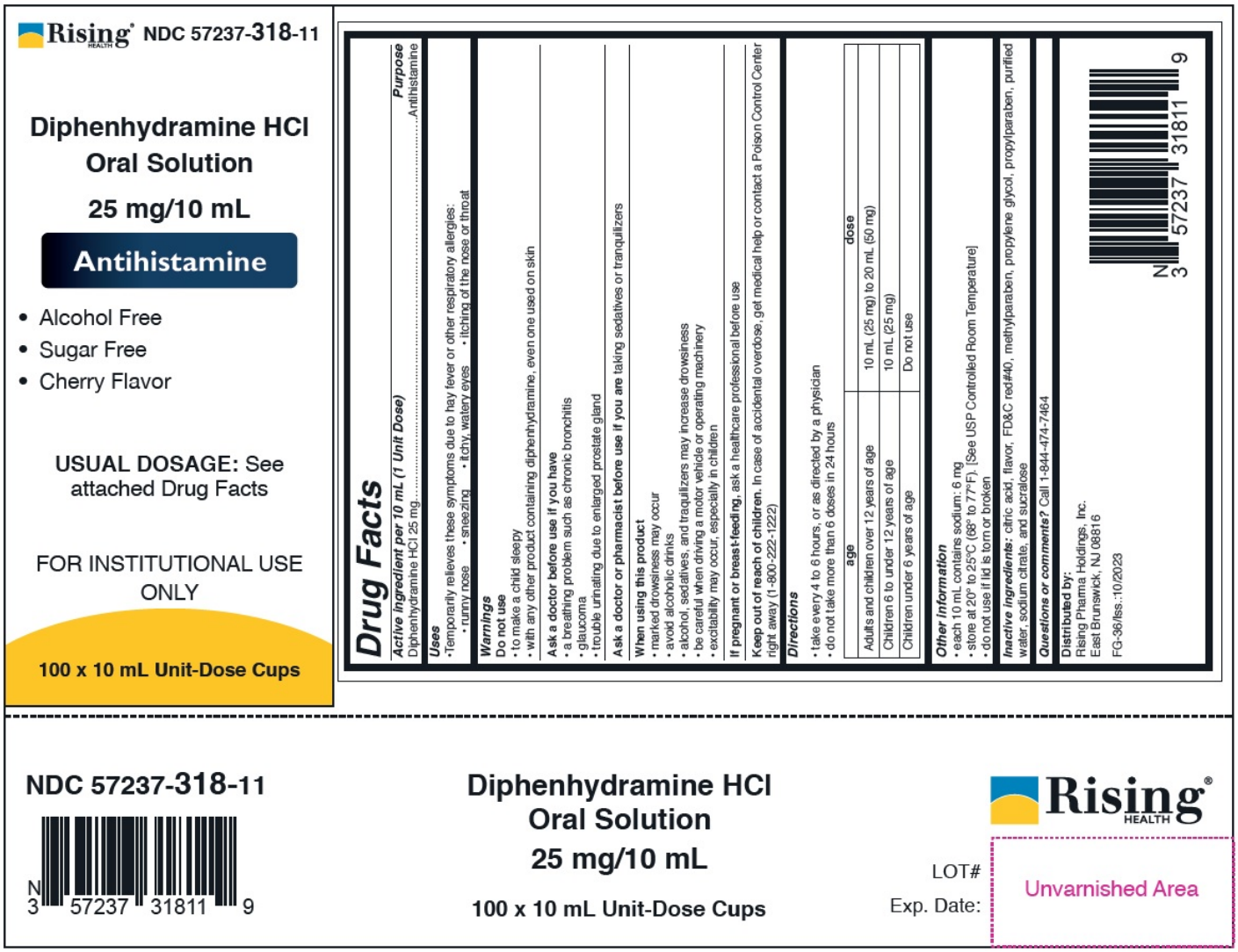
NDC 57237-318-01: 10 mL unit dose cup

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

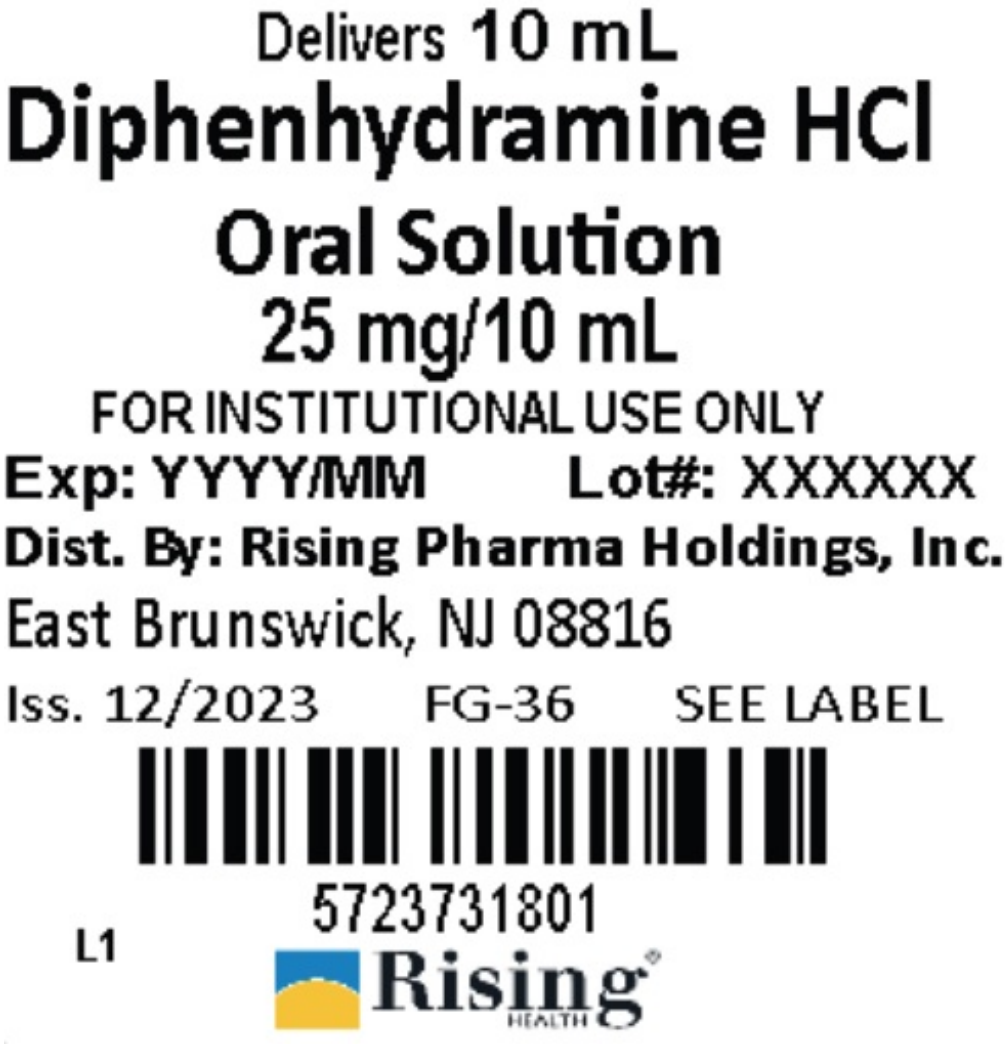
PRINCIPAL DISPLAY PANEL

25 mg/10 mL

Case Label NDC 57237-318-11



Lid Label NDC 57237-318-01



DIPHENHYDRAMINE HCL ORAL SOLUTION

diphenhydramine hcl oral solution

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 Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 10 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:57237-318-11	100 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	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	12/15/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Revised: 1/2024 Rising Pharma Holdings, Inc.