

**DIPHENHYDRAMINE HCL ORAL SOLUTION- diphenhydramine hcl oral solution
MAJOR® PHARMACEUTICALS**

Diphenhydramine HCl Oral Solution 12.5 mg/5 mL

Diphenhydramine HCl Oral Solution 25 mg/10 mL

Drug Facts

Active ingredient per 5 mL (1 Unit Dose)

Diphenhydramine HCl 12.5 mg

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 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

For the 5 mL Unit-Dose:

- 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)

Directions

For the 10 mL Unit-Dose:

- 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 6 years of age	Do not use
Children 6 to under 12 years of age	10 mL (25 mg)
Adults and children 12 years of age and over	10 mL (25 mg) to 20 mL (50 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? (855) 879-4368

Distributed by:

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

PRINCIPAL DISPLAY PANEL

MAJOR®

NDC 0904-7323-41

Each 5 mL Contains:

Diphenhydramine HCL Oral Solution

12.5 mg/5 mL

Antihistamine

Delivers 5 mL • See insert

For Institutional Use Only

Cherry Flavor

MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

Sugar Free • Alcohol Free



PRINCIPAL DISPLAY PANEL

MAJOR®

NDC 0904-7324-66

Each 10 mL Contains:

Diphendramine HCL Oral Solution

25 mg/10 mL

Antihistamine

Delivers 10 mL • See insert

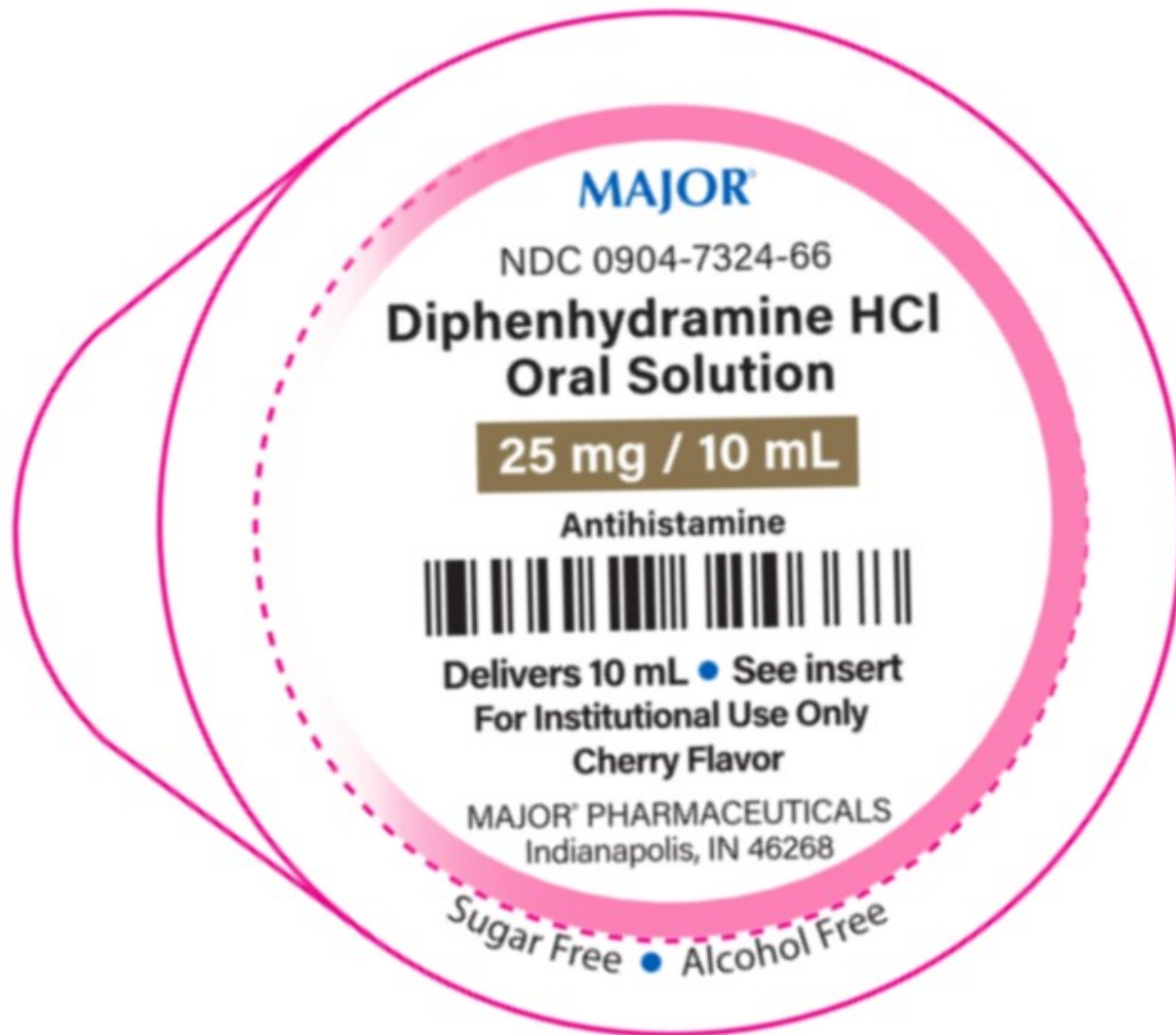
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Cherry Flavor

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Sugar Free • Alcohol Free



DIPHENHYDRAMINE HCL ORAL SOLUTION

diphenhydramine hcl oral solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-7323
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:0904-7323-70	100 in 1 BOX, UNIT-DOSE	01/22/2024	
1	NDC:0904-7323-41	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	M012	01/22/2024	

DIPHENHYDRAMINE HCL ORAL SOLUTION

diphenhydramine hcl oral solution

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Inactive Ingredients

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FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
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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:0904-7324-72	100 in 1 BOX, UNIT-DOSE	01/22/2024	
1	NDC:0904-7324-66	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	M012	01/22/2024	

Labeler - MAJOR® PHARMACEUTICALS (191427277)

Revised: 3/2024

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