

DIPHENHYDRAMINE HCL- diphenhydramine hcl solution
Preferred Pharmaceuticals Inc.

Major 44-015-DSP

Active ingredient (in each teaspoonful (5 mL))

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - o runny nose
 - o sneezing
 - o itchy, watery eyes
 - o 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 emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- marked drowsiness may occur
- use caution when driving a motor vehicle or operating machinery

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

- do not take more than 6 doses in 24 hours
- mL = milliliter; FL OZ = fluid ounce
- find right dose on chart below
- take every 4 to 6 hours, or as directed by a doctor

Age	Dose
adults and children 12 years and over	2 - 4 teaspoonsful (25 mg to 50 mg)
children 6 to 11 years	1 - 2 teaspoonsful (12.5 mg to 25 mg)
children 2 to 5 years	do not use unless directed by a doctor
children under 2 years	do not use

Other information

- **each teaspoonful (5 mL) contains:** sodium 5 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive ingredients

anhydrous citric acid, D&C red #33, FD&C red #40, flavors, glycerin, high fructose corn syrup, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sucrose

Questions or comments?

(800) 616-2471

Relabeled By: Preferred Pharmaceuticals Inc.

Principal display panel

MAJOR®

NDC 68788-8274-1

Relabeled By: Preferred Pharmaceuticals Inc.

**Diphenhydramine HCl
Oral Solution**

Antihistamine

12.5 mg/5 mL

Institutional Dispensing only

**Cherry Flavored
Alcohol Free**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING**



50844 REV1019A01521

Distributed by: **MAJOR® PHARMACEUTICALS**

Livonia, MI 48152

Rev. 03/21 M-17

Relabeled By: Preferred Pharmaceuticals Inc.

<p>Diphenhydramine HCl Oral Solution 12.5mg/5mL Generic for Children's Benadryl Active ingredient (in each 5mL): Diphenhydramine HCL 12.5mg...Antihistamin e Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: Major Pharm.; Livonia, MI Prod#: Warning <small>Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers. See bottle for complete list of drug facts and information. Keep out of reach of children. Alcohol Free. Cherry Flavored.</small></p>	 <p>Directions English Take ___ teaspoonful(s)) every ___ hours.</p>	 <p>Instrucciones Espanol: Toma ___ cucharita(s)) cada ___ horas</p>	<p><small>Zoom in (Ltri+Plus)</small> CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p> <p>Diphenhydramine HCl Oral Solution 12.5mg/5mL Qty: Ins: Lot#: Bat#: Prod# (NDC): Diphenhydramine HCl Oral Solution 12.5mg/5mL Qty: Ins: Lot#: Bat#: Prod# (NDC): Diphenhydramine HCl Oral Solution 12.5mg/5mL Qty: Insurance NDC: Lot#: Bat#: Diphenhydramine HCl Oral Solution 12.5mg/5mL Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>
			Log
			Chart
			Billing
			Patient

DIPHENHYDRAMINE HCL diphenhydramine hcl solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8274(NDC:0904-6985)
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCROSE (UNII: C151H8M554)	

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:68788-8274-1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	341	10/14/2022	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8274)

Revised: 4/2024

Preferred Pharmaceuticals Inc.