DIPHENHYDRAMINE HCL- diphenhydramine hcl solution
Major Pharmaceuticals

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:
  - 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 emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- marked drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- 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 directed**
- do not take more than 6 doses in 24 hours
- mL = milliliter
- 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 4 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, flavor, glycerin, high fructose corn syrup, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sucrose

Questions or comments?

1-800-426-9391

Principal display panel

MAJOR®

NDC 0904-6985-16

Diphenhydramine HCl
Oral Solution

Antihistamine

12.5 mg/5 mL

Cherry Flavored

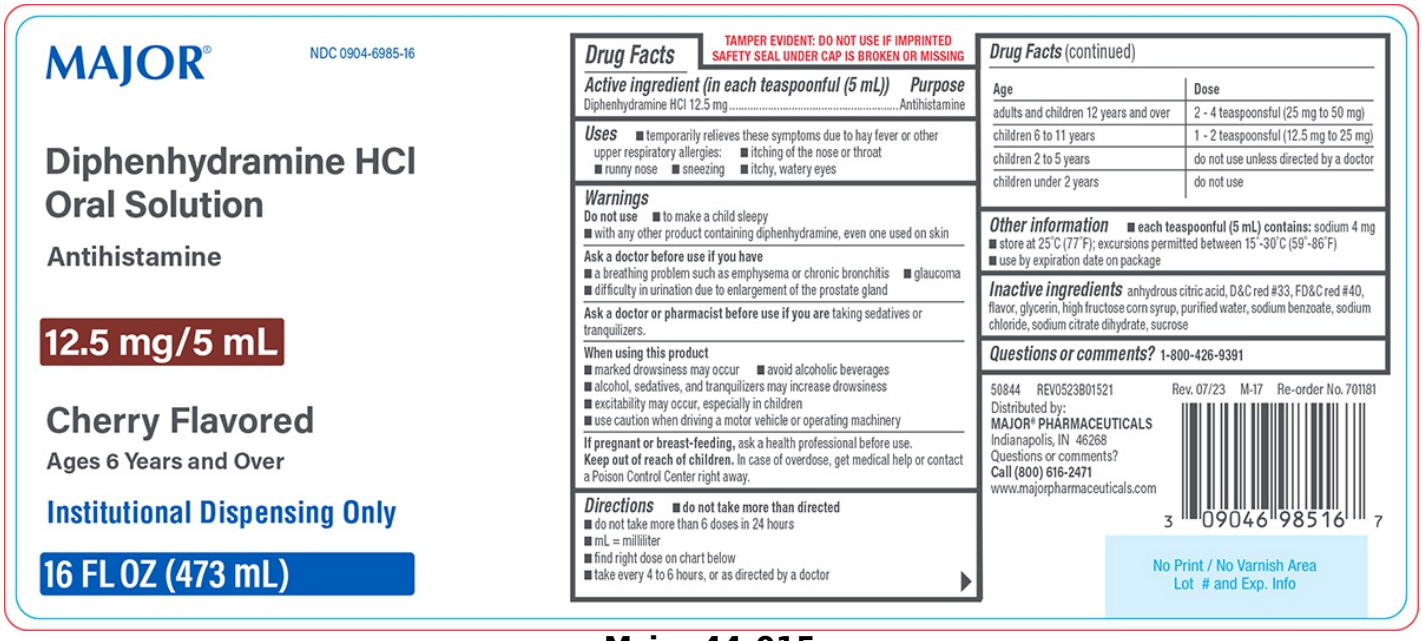
Ages 6 Years and Over

Institutional Dispensing only

16 FL OZ (473 mL)

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

50844 REV0523B01521
Distributed by:
MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268
Questions or comments?
Call (800) 616-2471
www.majorpharmaceuticals.com



Major 44-015

DIPHENHYDRAMINE HCL

diphenhydramine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:0904-6985-20	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/27/2019	
2	NDC:0904-6985-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/27/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/27/2019	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(0904-6985) , pack(0904-6985)

Revised: 8/2024 Major Pharmaceuticals