DIPHENHYDRAMINE HCL- diphenhydramine hcl liquid
ATLANTIC BIOLOGICALS CORP.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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
- 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

Principal Display Panel

NDC 17856-6985-01

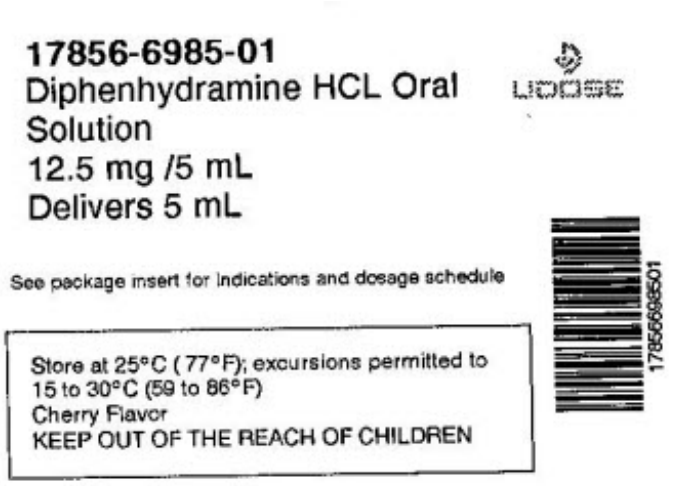
Diphenhydramine HCl
Oral Solution

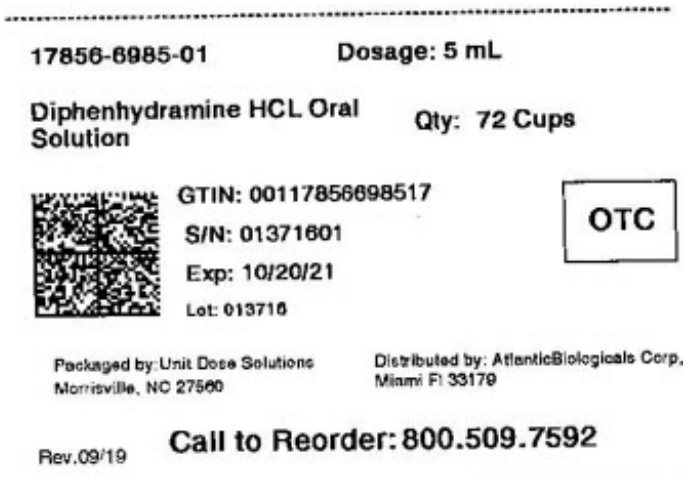
Antihistamine

12.5 mg/5 mL

Institutional Dispensing only

Cherry Flavored
Alcohol Free





NDC 17856-6985-02

Diphenhydramine HCl
Oral Solution

Antihistamine

25 mg/5 mL

Institutional Dispensing only

Cherry Flavored
Alcohol Free

DIPHENHYDRAMINE HCL

diphenhydramine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-6985(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:17856-6985-1	72 in 1 BOX, UNIT-DOSE	04/21/2021	
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-6985-2	72 in 1 BOX, UNIT-DOSE	04/21/2021	
2		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 final	part341	08/27/2019	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-6985) , relabel(17856-6985)

Revised: 4/2021 ATLANTIC BIOLOGICALS CORP.