

**CHILDRENS ALLERGY- diphenhydramine hydrochloride solution**  
**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.*

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**Drug Facts**

***Active ingredient [in each 5 mL]***

Diphenhydramine HCl, USP 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 the child has**

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- a sodium-restricted diet

**Ask a doctor or pharmacist before use if you**

**are** taking sedatives or tranquilizers

**When using this product**

- sedatives and tranquilizers may increase drowsiness
- marked drowsiness may occur
- excitability may occur, especially in children

**Keep out of reach of children.**

In case of 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 doctor
- do not take more than 6 doses in 24 hours
- mL = milliliter

Age (yr)	Dose (mL)
children under 6 years of age	ask a doctor
children 6 years to under 12 years of age	5 mL to 10 mL

**Attention:** Use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

**Other information**

- **each 5 mL contains:** sodium 9 mg
- store between 20-25°C (68-77°F). Protect from light. Store in outer carton until contents used
- see bottom panel for lot number and expiration date

**Inactive ingredients**

anhydrous citric acid, carboxymethyl cellulose sodium, flavor, glycerin, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution

**Questions or comments? 1-855-274-4122**

**Distributed By** ATLANTIC BIOLOGICALS CORP.

20101 N.E 16TH PLACE

MIAMI, FL 33179

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL**

**NDC 17856-0361-01**

**Compare to  
Children's Benadryl®  
active ingredient\***

**Children's  
ALLERGY  
Antihistamine  
diphenhydramine hydrochloride  
25mg/10 mL oral solution  
liquid medication**

**Relieves:**

- **Runny Nose**
- **Sneezing**
- **Itchy, Watery Eyes**
- **Itchy Throat**

**Sugar & Alcohol Free**

**Dye-Free** Bubble Gum Flavored

**17856-0361-01**  
**Children's ALLERGY**  
**(DIPHENYDRAMINE HCL**  
**ORAL SOLUTION)**  
**25MG/10ML**



Rev. 01/19

See package insert for indications and dosage schedule

Store between 20-25°C (68-77°F). Protect from light.  
Antihistamine, Sugar & Alcohol free/ Dye free  
\*\*\* Keep out of the reach of children\*\*\*\*

17856-0361-01

Dosage: 10ML

DIPHENYDRAMINE HCL

Qty: 72 CUPS



GTIN: 00117856036111

S/N: 00787400000001

Exp: 02/20/20

Lot: 007874

OTC



17856036101

Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: Atlantic Biological  
Corp, Miami FL 33179

Call to Reorder: 800.509.7592

NDC 17856-0361-02

Compare to  
**Children's Benadryl®**  
active ingredient\*

**Children's**  
**ALLERGY**

Antihistamine

**diphenhydramine hydrochloride**  
**12.5mg/5mL oral solution**  
**liquid medication**

Relieves:

**Runny Nose**  
**Sneezing**

**Itchy, Watery Eyes  
Itchy Throat  
Sugar & Alcohol Free**

**Dye-Free  
Bubble Gum Flavored**

**17856-0361-02  
Children's ALLERGY  
(DIPHENYDRAMINE HCL  
ORAL SOLUTION)  
12.5MG/5ML**



Rev.01/19

See package insert for indications and dosage schedule

Store between 20-25°C (68-77°F). Protect from light.  
Antihistamine, Sugar & Alcohol free/ Dye free  
\*\*\* Keep out of the reach of children\*\*\*\*

17856-0361-02      Dosage: 5ML

DIPHENYDRAMINE HCL      Qty: 72 CUPS



GTIN: 00117856036128  
S/N: 00787500000001  
Exp: 02/20/20  
Lot: 007875

**OTC**



17856036102

Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: AtlanticBiological  
Corp, Miami FL 33179

**Call to Reorder: 800.509.7592**

**CHILDRENS ALLERGY**

diphenhydramine hydrochloride solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-0361(NDC:46122-361)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL
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### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	

### Product Characteristics

Color	WHITE (Colorless)	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0361-1	72 in 1 BOX, UNIT-DOSE	01/20/2021	
1		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-0361-2	72 in 1 BOX, UNIT-DOSE	01/20/2021	
2		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 FINAL	part341	05/20/2016	

**Labeler** - ATLANTIC BIOLOGICALS CORP. (047437707)

### Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-0361) , repack(17856-0361)