

**CHILDRENS ALLERGY RELIEF- diphenhydramine hcl solution**  
**Cardinal Health 110, LLC. DBA Leader**

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**Leader 44-018**

***Active ingredient (in each 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 the child has**

- glaucoma
- a breathing problem such as chronic bronchitis

**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 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
- only use the dose cup provided
- find right dose on chart below
- take every 4 to 6 hours, or as directed by a doctor

<b>Age (yr)</b>	<b>Dose (mL)</b>
children under 2 years	do not use
children 2 to 5 years	do not use unless directed by a doctor
children 6 to 11 years	5 mL to 10 mL

### ***Other information***

- **each 5 mL contains:** sodium 4 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

anhydrous citric acid, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sucralose, xanthan gum

### ***Questions or comments?***

**1-800-426-9391**

### ***Principal Display Panel***

**LEADER™**

**NDC 70000-0701-1**

**DYE-FREE**

**Children's**

**Allergy**

**Relief**

Diphenhydramine HCl

12.5 mg / 5 mL Oral Solution

Antihistamine

**Clear**

**Bubble Gum**

Flavored Liquid

**Ages 6 to 11 Years**

**Relief of:**

Sneezing

Runny Nose

Itchy, Watery Eyes  
Itchy Throat  
or Nose  
Alcohol-Free  
Sugar-Free

**COMPARE TO  
CHILDREN'S  
BENADRYL®  
DYE-FREE  
ALLERGY LIQUID**

active ingredient\*

100% Money  
Back Guarantee

**4 FL OZ (118 mL)**

\*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Children's Benadryl® Dye-Free Allergy.  
50844                      ORG072401836

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

**CardinalHealth™**

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DUBLIN, OHIO 43017

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**Essential to Care™ since 1979**



**LEADER 44-018**

## CHILDRENS ALLERGY RELIEF

diphenhydramine hcl solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0701
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0701-1	1 in 1 CARTON	12/19/2024	
1		118 mL in 1 BOTTLE, PLASTIC; 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	12/19/2024	

**Labeler** - Cardinal Health 110, LLC. DBA Leader (063997360)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(70000-0701) , pack(70000-0701)

