

## **SOUND BODY CHILDRENS ALLERGY RELIEF- diphenhydramine hcl solution**

**Big Lots Stores, Inc.**

*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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### **Big Lots, Inc Children's Allergy Relief Drug Facts**

#### **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:
- sneezing
- itching of the nose or throat
- runny nose
- itchy, watery eyes

#### **Warnings**

##### **Do not use**

- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

##### **Ask a doctor before use if the child has**

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

##### **Ask a doctor or pharmacist before use if the child is**

taking sedatives or tranquilizers

##### **When using this product**

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

##### **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

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

Age (yr)	Dose (mL)
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

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 15 mg
- store at 20-25°C (68-77°F). Protect from light. Store in outer carton until contents used.
- do not use if printed neckband is broken or missing

## Inactive ingredients

anhydrous citric acid, D&C red #33, FD&C red #40, flavor, glycerin, high fructose corn syrup, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution

## Questions or comments?

1-800-719-9260

## Principal Display Panel

Compare to the Active Ingredient in Children's Benadryl® Allergy Liquid

RELIEF OF:

Runny Nose – Sneezing

Itchy, Watery Eyes

Itchy Throat or Nose

CHILDREN'S

Allergy Relief

Diphenhydramine HCl 12.5 mg / 5 mL Oral Solution

Antihistamine

4-6 HOURS/DOSE

ALCOHOL FREE

Cherry Flavor

4 FL OZ (118 mL)



## SOUND BODY CHILDRENS ALLERGY RELIEF

diphenhydramine hcl solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50594-013
<b>Route of Administration</b>	ORAL		

<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SORBITOL (UNII: 506T60A25R)				
GLYCERIN (UNII: PDC6A3C0OX)				
<b>Product Characteristics</b>				
<b>Color</b>	RED (Bluish-Red)	<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50594-013-26	1 in 1 CARTON	01/12/2016	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	01/12/2016		

**Labeler** - Big Lots Stores, Inc. (017885351)

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Big Lots Stores, Inc.