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.

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

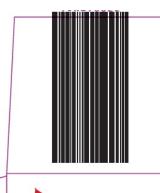
Antihistamine

4-6 HOURS/DOSE

ALCOHOL FREE

Cherry Flavor

4 FL OZ (118 mL)



Compare to the Active Ingredient in

Children's Benadryl® Allergy Liquid

12.5 mg / 5 mL Oral Solution

Antihistamine

ALCOHOL FREE

Cherry Flavor

4 FL 0Z

Runny Nose • Sneezing
 Itchy, Watery Eyes
 Itchy Throat or Nose

RELIEF OF:









Compare to the Active Ingredient in

Children's Benadryl® Allergy Liquid*

12.5 mg / 5 mL Oral Solution

Antihistamine

ALCOHOL FREE

Cherry Flavor

4 FL 0Z

 $(118 \, mL)$

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Runny Nose • Sneezing

Itchy, Watery Eyes

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- even one used on skin

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- glaucoma a sodium-restricted diet

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Drug Facts (continued)

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flavor, glycerin, high fructose com syrup,
poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sorbitol solution

Questions or comments? 1-800-719-9260

GLUTEN FREE

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Benadryl® Allergy Liquid.

Distributed By: Perrigo Company 515 Eastern Avenue Allegan, Michigan 49010 V#5003185 ITEM#37926





LOT NO.

EXP.

: 37926 TM C4

SOUND BODY CHILDRENS ALLERGY RELIEF

diphenhydramine hcl solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50594-013

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US 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)		

Product Characteristics			
Color	RED (Bluish-Red)	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50594-013-26	1 in 1 CARTON	0 1/12/20 16	
1	118 mL in 1 BOTTLE; 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	0 1/12/20 16	

Labeler - Big Lots Stores, Inc. (017885351)

Revised: 8/2017 Big Lots Stores, Inc.