# SOUND BODY NIGHTTIME SLEEP AID- 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 Nighttime Sleep-Aid Drug Facts

#### Active ingredient (in each 30 mL)

Diphenhydramine HCl 50 mg

## Purpose

Nighttime sleep-aid

#### Uses

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

### Warnings

#### Do not use

- for children under 12 years of age
- 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 an 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

### Stop use and ask a doctor if

sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

## 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 (1-800-222-1222).

#### **Directions**

- take only one dose per day (24 hours)
- only use dose cup provided

adults & children 12 yrs & over	30 mL at bed time if needed or as directed by a doctor
children under 12 yrs	do not use

#### Other information

- each 30 mL dose cup contains: sodium 20 mg
- store at 20-25°C (68-77°F)

## **Inactive Ingredients**

alcohol, anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, poloxamer 407, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate

#### Questions or comments?

1-800-719-9260

## Package/Label Principal Display Panel

Compare to the Active Ingredient in Vicks  $\mbox{\ensuremath{\mathbb{R}}}$  ZzzQuil  $\mbox{\ensuremath{\mathbb{R}}}$ 

Nighttime Sleep-Aid

Diphenhydramine HCl

50 mg per 30 mL

Not for treating Cold or Flu

NON-HABIT FORMING

#1 DOCTOR RECOMMENDED

10% ALCOHOL

**BERRY FLAVOR** 

sleep-aid active ingredient

12 FL OZ (355 mL)

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: 18640 TM F2

## SOUND BODY NIGHTTIME SLEEP AID

diphenhydramine hcl solution

Drug Facts (continued)

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\*This product is not manufactured or distributed by

Procter & Gamble, distributor of Vicks® ZzzQuil®.

†Of U.S. physicians surveyed by an independent

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12 yrs & over

**GLUTEN FREE** 

market research firm.

V#5003185 ITEM#18640

Distributed By: Perrigo Company

515 Eastern Ávenue, Allegan, Mí 49010

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50594-008

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE	DIPHENHYDRAMINE	50 mg	
- UNII:8GTS82S83M)	HYDROCHLORIDE	in 30 mL	

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q 16 7 V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)	
SO DIUM BENZO ATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Product Characteristics			
Color	PURPLE	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1 NDC:50594-008-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/21/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	04/21/2015	

Labeler - Big Lots Stores, Inc. (017885351)

Revised: 9/2017 Big Lots Stores, Inc.