

**SLEEP AID- diphenhydramine hcl liquid**  
**Harmon Store 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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**Core Values 44-002A**

***Active ingredient***  
***(in each 30 mL dose cup)***

Diphenhydramine HCl 50 mg

***Purpose***

Nighttime sleep-aid

***Uses***

- for 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 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 a 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 (1-800-222-1222) right away.

***Directions***

- **do not take more than directed**
- mL = milliliter; TBSP = tablespoon; FL OZ = fluid ounce
- use only enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- take only one dose per day (24 hours)
- adults and children 12 years and over: take 30 mL (2 TBSP) in the dosing cup provided at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

#### ***Other information***

- **each 30 mL dose cup contains:** sodium 17 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

#### ***Inactive ingredients***

anhydrous citric acid, FD&C blue #1, FD&C red # 40, flavor, glycerin, high fructose corn syrup, propylene glycol, purified water, sodium benzoate, sodium chloride, sodium citrate dihydrate, sucralose, sucrose, xanthan gum

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

**1-800-426-9391**

#### ***Principal display panel***

**CORE VALUES™**

Compare to the active ingredient in Vicks® ZzzQuil® NIGHTTIME SLEEP-AID †

Nighttime

Sleep Aid

Diphenhydramine HCl /

Nighttime Sleep Aid

- Non-habit forming
- Alcohol free

12 FL OZ (355 mL) berry flavor

**TAMPER EVIDENT: DO NOT USE IF PRINTED NECK WRAP IS BROKEN OR MISSING**

†This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark VICKS® ZzzQuil® NIGHTTIME SLEEP-AID.

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**Drug Facts (continued)**

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*No Print / No Varnish Area  
Lot # and Exp. Info*

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# CORE VALUES™

Compare to the active ingredient in Vicks® ZzzQuil® NIGHTTIME SLEEP-AID\*

## Nighttime Sleep Aid

### Diphenhydramine HCl / Nighttime Sleep Aid

- Non-habit forming
- Alcohol free



berry flavor

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**12 FL OZ (355 mL)**

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Core Values 44-002A

SLEEP AID			
diphenhydramine hcl liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-200
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0K00R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

**Product Characteristics**

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-200-02	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2018	
2	NDC:63940-200-45	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	10/01/2018	

**Labeler** - Harmon Store Inc. (804085293)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	MANUFACTURE(63940-200) , PACK(63940-200)