# NIGHTTIME SLEEP AID- diphenhydramine hcl capsule, liquid filled CVS Pharmacy

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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#### CVS 44-656

#### Active ingredient (in each liquid-filled capsule)

Diphenhydramine HCl 50 mg

#### Purpose

Nighttime sleep-aid

#### Use

for relief of occasional sleeplessness

# 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

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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

• adults and children 12 years and over: 1 capsule (50 mg) at bedtime if needed, or as directed by a

doctor

#### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid excessive heat
- use by expiration date on package

#### **Inactive ingredients**

edible white ink, FD&C blue #1, gelatin, glycerin, lecithin, mineral oil, polyethylene glycol, purified water, sorbitol

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

 $\verb]1-800-426-9391]$ 

**Principal Display Panel** 

CVS Health™

Compare to the active ingredient in Unisom<sup>®</sup> SleepGels<sup>®</sup>\*

#### Softgels

NDC 59779-956-46

Nighttime Sleep-Aid

#### **DIPHENHYDRAMINE HCl 50 mg**

Nighttime sleep-aid

- Fall asleep fast
- Easy to swallow

Actual Size

96 LIQUID-FILLED CAPSULES

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

\*This product is not manufactured or distributed by Chattern, Inc., owner of the registered trademark Unisom<sup>®</sup> SleepGels<sup>®</sup>. 50844 ORG031565646

#### Distributed by: CVS Pharmacy, Inc.

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**CVS<sup>®</sup>** Quality

#### Money Back Guarantee



Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-956
Route of Administration	ORAL		

Active Ingredient/Active Moiety					
Ingredient Name	<b>Basis of Strength</b>	Strength			
<b>DIPHENHYDRAMINE HYDRO CHL O RIDE</b> (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - UNII:8 GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg			
Inactive Ingredients					

Ingredient Name

Strength

FD&C BLUE NO. 1 (U					
,					
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)					
GLYCERIN (UNII: PDC					
MINERAL OIL (UNII:			• >		
		L, UNSPECIFIED (UNII: 3WJQ0SDW1	A)		
WATER (UNII: 059QF					
SORBITOL (UNII: 506		,			
LECITHIN, SO YBEAN	I (UNI	I: 1DI56QDM62)			
Product Character	eristi				
Color		BLUE (clear)	Score		no score
Shape		OVAL	Size		13mm
Flavor			Imprint Code		656
Contains					
Packaging					
# Item Code		Package Description		Marketing Start Date	<b>Marketing End Date</b>
1 NDC:59779-956-19	1 in 1	CARTON		0 3/0 1/20 15	10/20/2019
1	1 8 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2 NDC:59779-956-46	-46 96 in 1 BOTTLE; Type 0: Not a Combination Product		0 3/0 1/20 15		
		•			
Marketing Information					
Marketing Catego	ry	Application Number or Monogr	aph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FI	NAL	part338		0 3/0 1/20 15	

# Labeler - CVS Pharmacy (062312574)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd		421293287	API MANUFACTURE(59779-956)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		967626305	PACK(59779-956)	

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	PACK(59779-956)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		868734088	PACK(59779-956)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		038154464	PACK(59779-956)	

Revised: 7/2019

**CVS** Pharmacy