

## **SLEEP-AID NIGHTTIME- diphenhydramine hcl capsule**

**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 44-682**

### ***Active ingredient (in each mini-capsule)***

Diphenhydramine HCl 25 mg

### ***Purpose***

Nighttime sleep-aid

### ***Uses***

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**

- 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***

- adults and children 12 years and over: take 2 mini-capsules (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)
- see end flap for expiration date and lot number
- protect from moisture

**Inactive ingredients**

butylparaben, corn starch, FD&C blue #1, FD&C red #3, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, povidone, propylene glycol, propylparaben, shellac, silicon dioxide, sodium hydroxide, titanium dioxide

**Questions or comments?**

**1-800-426-9391**

**Principal display panel**

CVS Health™

Compare to the active ingredient in Unisom® SleepMinis™\*

Mini-Capsules

NDC 69842-682-11

Nighttime

**Sleep-Aid**

**DIPHENHYDRAMINE HCl, 25 mg**

Nighttime sleep-aid

Non-habit forming

**60 MINI-CAPSULES**

Actual Size

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING OR IF BLUE BAND AROUND CAPSULE IS BROKEN OR MISSING**

\*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® SleepMinis™.

50844      ORG021668211

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

One CVS Drive, Woonsocket, RI 02895

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Money Back Guarantee



Mini-Capsules

NDC 69842-682-11

Nighttime

# Sleep-Aid

DIPHENHYDRAMINE HCl, 25 mg

Nighttime sleep-aid

Non-habit forming



Actual Size



60 MINI-CAPSULES

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING OR IF BLUE BAND AROUND CAPSULE IS BROKEN OR MISSING

#213598

FPO 80%

UPC# 050428564387

X XXXXXX XXXXXX X

No print/No varnish  
Lot & Exp date

60 MINI-CAPSULES

Non-habit forming

Nighttime sleep-aid

DIPHENHYDRAMINE HCl, 25 mg

## Sleep-Aid

Nighttime



CVS Health.

Compare to the active ingredient in Unisom® SleepMinis™ Mini-Capsules

NDC 69842-682-11

Nighttime

# Sleep-Aid

DIPHENHYDRAMINE HCl, 25 mg

Nighttime sleep-aid

Non-habit forming



Actual Size



60 MINI-CAPSULES

B-0231-682-11-H  
OR6021668211

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Unisom® SleepMinis™

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Drug Facts (continued)  
Questions or comments?  
1-800-426-9391

Drug Facts (continued)  
Other Information  
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)  
■ see end flap for expiration date and lot number  
■ protect from moisture  
**Inactive Ingredients** butylparaben, corn starch, FD&C blue #1, FD&C red #3, gelatin, lactose, magnesium stearate, methylparaben, polysorbate 80, povidone, propylene glycol, propylparaben, shellac, silicon dioxide, sodium hydroxide, titanium dioxide

Drug Facts (continued)  
■ 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**  
■ adults and children 12 years and over: take 2 mini-capsules (50 mg) at bedtime if needed, or as directed by a doctor

Drug Facts (continued)  
**Drug Facts**  
FOR COMPLETE PRODUCT INFORMATION  
KEEP OUTER PACKAGE  
**Active ingredient (in each mini-capsule)**  
Diphenhydramine HCl 25 mg... Nighttime sleep-aid  
**Purpose**  
Use for relief of occasional sleeplessness  
Do not use ■ for children under 12 years of age  
**Warnings**

CS275  
Z FOLD

**SLEEP-AID NIGHTTIME**

diphenhydramine hcl capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-682
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>BUTYL PARABEN</b> (UNII: 3QP1U3FV8)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>LACTOSE, UNSPECIFIED FORM</b> (UNII: J2B2A4N98G)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

**Product Characteristics**

<b>Color</b>	BLUE (with a light blue band)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	44;682
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-682-11	1 in 1 CARTON	07/31/2016	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-682-51	365 in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	07/31/2016	

**Labeler** - CVS Pharmacy (062312574)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(69842-682)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(69842-682) , PACK(69842-682)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(69842-682)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(69842-682)

Revised: 11/2019

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