# SLEEP-AID CHEWABLES NIGHTTIME- diphenhydramine hcl tablet, chewable CVS PHARMACY

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CVS 44-685-Sleep Aid

### Active ingredient (in each chewable tablet)

Diphenhydramine HCl 25 mg

#### **Purpose**

Nighttime sleep-aid

#### Uses

- reduces time to fall asleep if you have difficulty falling asleep
- 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 right away.

#### **Directions**

- do not take more than directed
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- take only one dose per day (24 hours)
- adults and children 12 years and over: 2 chewable tablets at bedtime if needed, or as directed by a doctor
- children under 12 years: do not use

#### Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

#### Inactive ingredients

D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose

#### Questions or comments?

1-800-426-9391

### Principal display panel

**CVS**Health®

**Nighttime** 

Sleep-Aid Chewables

# DIPHENHYDRAMINE HCI, 25 mg CHEWABLE TABLETS

Nighttime sleep-aid

### Non-habit forming tablets

- For a restful night's sleep
- Not for treating pain, cold or flu

Grape Flavor

#### **18** CHEWABLE TABLETS

Chew or crush tablets completely before swallowing.

#### **Actual Size**

# TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

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Drug Facts (continued)

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bis-qeek emdfrigiði. Diphen hydramine HCl 25 mg. (in each chewable tablet) Purpose Active ingredient

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

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CVSHealth.

Sleep-Aid Chewables

DIPHENHYDRAMINE HCI, 25 mg CHEWABLE TABLETS

REV0119B68544

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Directions

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Drug Facts (continued)

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Grape Flavor

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# **SLEEP-AID CHEWABLES NIGHTTIME**

diphenhydramine hcl tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-958	
Route of Administration	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		
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)			
<b>D&amp;C RED NO. 30</b> (UNII: 2S42T2808B)			
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)			
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)			
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MANNITOL (UNII: 30WL53L36A)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
SUCROSE (UNII: C151H8M554)			

Product Characteristics				
Color	purple	Score	no score	
Shape	ROUND	Size	13mm	
Flavor	GRAPE	Imprint Code	44;685	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69842-958- 44	3 in 1 CARTON	07/31/2018		
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product			

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	07/31/2018	

# Labeler - CVS PHARMACY (062312574)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		832867837	pack(69842-958)	

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	manufacture(69842-958)	

Revised: 12/2023 CVS PHARMACY