

**SLEEP-AID CHEWABLES NIGHTTIME- diphenhydramine hcl tablet, chewable**  
**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 44-685-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 (1-800-222-1222) 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***

CVSHealth™

Compare to the active ingredient in  
VICKS® ZzzQuil®\*

Nighttime

**Sleep-Aid**

**Chewables**

**DIPHENHYDRAMINE HCl, 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**

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

50844 REV0119A68544

**DO NOT USE IF INDIVIDUAL BLISTER UNITS ARE BROKEN OR OPEN.**

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This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark VICKS® ZzzQuil®.  
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**Drug Facts (continued)**  
**Questions or comments?** 1-800-426-9391

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

**Drug Facts**  
**KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

**Active ingredient (in each chewable tablet)**  
 Diphenhydramine HCl 25 mg..... 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.

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 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.

**Other information**  
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**Inactive ingredients** D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrans hydrated, edylcellulose, FD&C blue #1 aluminum lake, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose

**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

**Purpose**  
 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.

**DO NOT USE IF INDIVIDUAL BLISTER UNITS ARE BROKEN OR OPEN.**

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No Print/No Varnish  
 Lot and Expiration No.



**Nighttime Sleep-Aid Chewables**  
 DIPHENHYDRAMINE HCl, 25 mg  
**CHEWABLE TABLETS**  
 Nighttime sleep-aid  
 Non-habit forming tablets



B-0231-685-44-ZH  
 REV0119A68544

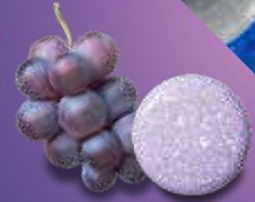


Compare to the active ingredient in VICKS® ZzzQuil®

**Nighttime Sleep-Aid Chewables**  
 DIPHENHYDRAMINE HCl, 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**

Actual Size

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**SLEEP-AID CHEWABLES NIGHTTIME**

diphenhydramine hcl tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-958
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	

**Product Characteristics**

<b>Color</b>	PURPLE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	44;685
<b>Contains</b>			

**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 FINAL	part338	07/31/2018	

**Labeler** - CVS Pharmacy (062312574)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	MANUFACTURE(69842-958) , PACK(69842-958)

Revised: 12/2019

CVS Pharmacy