

## **SLEEP-AID NIGHTTIME- 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 44-658-Sleep Aid**

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

Diphenhydramine HCl 25 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**

- 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***

- **do not take more than directed**

- take only one dose per day (24 hours)
- adults and children 12 years and over: take 2 capsules 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**
- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from heat, humidity and light

***Inactive ingredients***

edible white ink, gelatin, glycerin, polyethylene glycol, purified water, sorbitol

***Questions or comments?***

**1-800-426-9391**

***Principal display panel***

**CVSHealth™**

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

NDC 69842-658-08

Nighttime

**Sleep-Aid**

**DIPHENHYDRAMINE HCl, 25 mg** - Nighttime sleep-aid

**Free of artificial dyes & preservatives**

Non-habit forming capsules  
Relieves occasional sleeplessness

**24 LIQUID-FILLED CAPSULES**

Actual Size

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

50844 ORG081765808

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

One CVS Drive, Woonsocket, RI 02895

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V-11112

**CVS Quality**

Money Back Guarantee

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

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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50844 ORG081765908

Free of artificial dyes & preservatives

Nighttime  
**Sleep-Aid**  
DIPHENHYDRAMINE HCl, 25 mg  
Nighttime sleep-aid



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|   |  |  |
|---|--|--|
| <p><b>Drug Facts</b> (continued)</p> <p><b>Active ingredient</b><br/>(in each liquid-filled capsule)<br/>Diphenhydramine HCl 25 mg ...<br/>Nighttime sleep-aid</p> <p><b>Purpose</b><br/>Nighttime sleep-aid</p>  | <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>For relief of occasional sleeplessness</li> <li>reduces time to fall asleep if you have difficulty falling asleep</li> </ul>   | <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>Do not use</li> <li>for children under 12 years of age</li> <li>with any other product containing diphenhydramine, even one used on skin</li> <li>Ask a doctor before use if you have             <ul style="list-style-type: none"> <li>glaucoma</li> <li>a breathing problem such as emphysema or chronic bronchitis</li> <li>difficulty in urination due to enlargement of the prostate gland</li> </ul> </li> <li>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</li> </ul> <p>When using this product avoid alcoholic beverages.</p> <p>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.</p> |
| <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>do not take more than directed</li> <li>take only one dose per day (24 hours)</li> <li>adults and children 12 years and over: take 2 capsules at bedtime if needed or as directed by a doctor</li> <li>children under 12 years: do not use</li> </ul> | <p><b>Other information</b></p> <ul style="list-style-type: none"> <li><b>TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN</b> ■ see end flap for expiration date and lot number</li> <li>store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)</li> <li>protect from heat, humidity and light</li> </ul> | <p><b>Inactive ingredients</b><br/>edible white ink, gelatin, glycerin, polyethylene glycol, purified water, sorbitol</p> <p><b>Questions or comments?</b> 1-800-426-9391</p>  |

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION



Nighttime  
**Sleep-Aid**  
DIPHENHYDRAMINE HCl, 25 mg  
Nighttime sleep-aid

Free of artificial dyes & preservatives

B-0231-658-08-07H  
09/08/17/5888



Compare to the active ingredient in ZzzQuil® LiquiCaps®  
NDC 69842-658-08

Nighttime  
**Sleep-Aid**

DIPHENHYDRAMINE HCl, 25 mg - Nighttime sleep-aid

Free of artificial dyes & preservatives

Non-habit forming capsules  
Relieves occasional sleeplessness



24 LIQUID-FILLED CAPSULES

C4147R

**SLEEP-AID NIGHTTIME**

diphenhydramine hcl capsule, liquid filled

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69842-658 |
| <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 |
|---|----------|
| GELATIN (UNII: 2G86QN327L)                          |          |
| GLYCERIN (UNII: PDC6A3C0OX)                         |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |
| WATER (UNII: 059QF0KO0R)                            |          |
| SORBITOL (UNII: 506T60A25R)                         |          |

**Product Characteristics**

|                 |                |                     |          |
|-----------------|----------------|---------------------|----------|
| <b>Color</b>    | YELLOW (clear) | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL           | <b>Size</b>         | 15mm     |
| <b>Flavor</b>   |                | <b>Imprint Code</b> | 658      |
| <b>Contains</b> |                |                     |          |

**Packaging**

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69842-658-08 | 1 in 1 CARTON   | 01/15/2018           | 01/10/2023         |
| 1 |                  | 24 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                                  | 01/15/2018           | 01/10/2023         |

| <b>Establishment</b>    |                |               |                            |
|-------------------------|----------------|---------------|----------------------------|
| <b>Name</b>             | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| LNK International, Inc. |                | 832867837     | PACK(69842-658)            |

Revised: 3/2020

CVS Pharmacy