

**NIGHTTIME SLEEP AID- diphenhydramine hcl liquid  
Care One (Retail Business Services, LLC.)**

*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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**Drug Facts**

**Active ingredient (in each 30 mL)**

Diphenhydramine HCL 50 mg

**Purpose**

Nighttime sleep-aid

**Uses**

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

**Warnings**

**Do not use**

- with any other product containing diphenhydramine, even one used on the skin
- for children under 12 years of age

**Ask a doctor before use if you have**

- a breathing problem such as emphysema, or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged 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 serious underlying medical illness.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions**

- take only one dose per day (24 hours)
- mL=milliliter
- keep dosing cup with product
- measure only with dosing cup provided. Do not use any other dosing device
- adults and children 12 years and over
  - one dose=30 mL at bedtime if needed, or as directed by a doctor
- children under 12 years do not use

**Other information**

- **each 30 mL contains:** sodium 23 mg
- store between 20-25°C (68-77°F). Do not refrigerate
- protect from light

**Inactive ingredients**

citric acid, ethyl alcohol, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, polyoxyl 40 stearate, propylene glycol, purified water, saccharin sodium, sodium benzoate, trisodium citrate dihydrate

**Questions or comments?**

Call **1-877-753-3935** Monday-friday 9AM-5PM EST

**Principal Display Panel**

Compare to the Active Ingredient in ZZZQUIL®\*

**NIGHTTIME SLEEP AID**

Diphenhydramine HCL, 50 mg

Alcohol 10%

Non-Habit-Forming

Not for treating cold or flu

Berry Flavor

FL OZ (mL)

Failure to follow these warnings could result in serious consequences

\*This product is not manufactured or distributed by The Procter & Gamble Company. ZZZQUIL® is a registered trademark of The Procter & Gamble Company.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.**

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FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

## Package Label

← PEEL HERE **Drug Facts** (continued under label)

Failure to follow these warnings could result in serious consequences.

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient</b> (in each 30 mL) Diphenhydramine HCl 50 mg.....	Nighttime sleep-aid

**Uses**

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**Warnings**

**Do not use** ■ in children under 12 years of age  
■ with any other product containing diphenhydramine, even one used on skin

**CAREone™** NDC 72476-034-06  
*Compare to the Active Ingredient in ZZZQUIL®*

**NIGHTTIME SLEEP AID**  
**Diphenhydramine HCl, 50mg**

Alcohol 10%  
Non Habit-Forming  
Not for treating cold or flu

**Berry Flavor**  
**6 FL OZ (177mL)**

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.**

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**Drug Facts** (continued)

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**Drug Facts** (continued)

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**CARE ONE Nighttime Sleep Aid**

## NIGHTTIME SLEEP AID

diphenhydramine hcl liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-034
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLYOXYL 40 STEARATE</b> (UNII: 13A4J4NH9I)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM ANHYDROUS</b> (UNII: I4807BK602)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-034-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2019	06/30/2025
2	NDC:72476-034-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2019	06/30/2025

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	06/30/2019	06/30/2025

Revised: 1/2023

Care One (Retail Business Services, LLC.)