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.

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

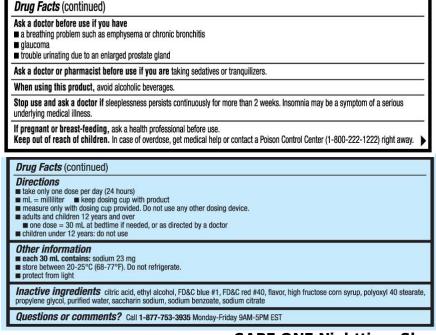
*This product is not manufactured or distributed by The Procter & Gamble Company. ZZZQUIL® is a registered trademark of The Procter & Gamble Company.

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

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Package Label





CARE ONE Nighttime Sleep Aid

NIGHTTIME SLEEP AID

diphenhydramine hcl liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72476-034

Route of Administration ORAL

Active Ingredient/Active Moiety

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

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

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

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

Marketing In	arketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	06/30/2019	06/30/2025	

Labeler - Care One (Retail Business Services, LLC.) (967989935)

Revised: 1/2023

Care One (Retail Business Services, LLC.)