NIGHTTIME SLEEP AID- diphenhydramine hcl liquid Care One (American Sales Company)

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
- with other drugs that cause drowsiness such as antihistamines, nighttime cold/flu products, and other nighttime sleep-aids

Ask a doctor before use if you have

- heart disease
- glaucoma
- breathing problem such as asthma, emphysema, or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers or any other sleep-aid.

When using this product

- drowsiness will occur
- avoid alcoholic drinks and other drugs that cause drowsiness
- be careful when driving a motor vehicle or operating machinery

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: Taking more than directed can cause serious health problems. in case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take only one dose per day (24 hours) (see overdose warning)
- mL=milliliter
- measure only with dosing cup provided.Do not use any other dosing device
- keep dosing cup with product
- 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 at 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 HCI 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

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

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

DISTRIBUTED BY

FOODHOLD USA LLC

LANDOVER, MD 20785

1-877-846-9949

Package Label



NIGHTTIME SLEEP AID diphenhydramine hcl liquid					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-034		
Route of Administration	ORAL				
Active Ingredient/Active Moiety					

Ingred	ient Name		Basis of Strengt	th Str	ength
DIPHENHYDRAMINE HYDROCHLO (DIPHENHYDRAMINE - UNII:8GTS82S8		40)	DIPHENHYDRAMINE HYDROCHLORIDE	50 m in 3	ng 0 mL
Inactive Ingredients					
	Ingredient Nam	е		Strength	
ANHYDROUS CITRIC ACID (UNII: X	F417D3PSL)				
PROPYLENE GLYCOL (UNII: 6DC9Q	167V3)				
POLYOXYL 40 STEARATE (UNII: 13	A4J4NH9I)				
WATER (UNII: 059QF0KO0R)					
SODIUM BENZOATE (UNII: OJ245FE	5EU)				
SACCHARIN SODIUM ANHYDROUS	5 (UNII: I4807BK602)				
TRISODIUM CITRATE DIHYDRATE	(UNII: B22547B95K)				
HIGH FRUCTOSE CORN SYRUP (U	NII: XY6UN3QB6S)				
FD&C BLUE NO. 1 (UNII: H3R47K31	BD)				
ALCOHOL (UNII: 3K9958V90M)					
FD&C RED NO. 40 (UNII: WZB9127	XOA)				
Product Characteristics					
Color		Score			
Shape		Size			
Flavor	BERRY	Imprint Code			
Contains					

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520- 034-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015	
2	NDC:41520- 034-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2015	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	06/30/2015	

Labeler - Care One (American Sales Company) (809183973)

Revised: 3/2024