

**SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled**  
**PuraCap Pharmaceutical 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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**Sleep-Aid**

**Drug Facts**

**Active ingredient (in each softgel)**

Diphenhydramine HCl 25 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**

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

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

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers or any other sleep-aid

**When using this product**

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- 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**

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adults & children 12 yrs & over	2 softgels at bedtime if needed or as directed by a doctor
childreb under 12 yrs	do not use

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### **Other information**

- store at 15°-30° C (59°-86° F)
- avoid excessive heat above 40° C (104° F) and high humidity
- protect from light

### **Inactive ingredients**

FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

### **Questions or comments?**

Call toll free: **1-855-215-8180**

### **PRINCIPAL DISPLAY PANEL**

Nighttime Sleep-Aid 96 SOFTGELS

NDC 51013-419-57

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



## SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-419
Route of Administration	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
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

**Product Characteristics**

Color	purple (clear)	Score	no score
Shape	capsule (oblong)	Size	15mm
Flavor		Imprint Code	PC11
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-419-57	8 in 1 CARTON	09/25/2017	
1		12 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	09/25/2017	

**Labeler** - PuraCap Pharmaceutical LLC (962106329)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(51013-419) , analysis(51013-419)