

**NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled**  
**PuraCap Pharmaceutical LLC**

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**Diphenhydramine Hydrochloride**

**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

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

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- 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 drinks

**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.**

In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- take only one dose per day (24 hours)

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

### Other information

- store at room temperature 15°-30° C (59°-86° F)
- avoid excessive heat above 40° C (104° F)
- 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

Diphenhydramine HCl 25mg

100 SOFTGELS

Compare to Active Ingredient in VICKS<sup>®</sup> ZzzQuil<sup>™</sup> NIGHTTIME SLEEP-AID LiquiCaps<sup>™</sup>

NDC 51013-181-01

**100 SOFTGELS**

**Nighttime**

**Sleep-Aid**

Diphenhydramine HCl  
25 mg

**PuraVation<sup>®</sup>** NDC 51013-181-01

Actual Size

Compare to Active Ingredient in VICKS<sup>®</sup> ZzzQuil<sup>™</sup> NIGHTTIME SLEEP-AID LiquiCaps<sup>™</sup>

**DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Drug Facts**

<b>Drug Facts</b> (continued)	
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†This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® ZzzQuil™, and LiquiCaps™.

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PC07-00

**Drug Facts (continued under label)**

Distributed by: PuraCap  
Pharmaceutical LLC  
Bridgewater, NJ 08807

Made in China



Lot No.:

Exp. Date:

**NIGHTTIME SLEEP AID**

diphenhydramine hydrochloride capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51013-181
<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
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	purple (clear)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (oblong)	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	PC11
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-181-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	11/30/2024	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(51013-181)

Revised: 11/2024

PuraCap Pharmaceutical LLC