#### NIGHTTIME SLEEP AID- diphenhydramine hcl 50mg capsule, liquid filled PuraCap Pharmaceutical LLC

-----

#### Diphenhydramine HCI 50mg

Drug Facts

### Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

### Purpose

Nighttime sleep-aid

### Use

• for the relief of occasional sleeplessness

### 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
- trouble urinating due to enlarged 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

• adults and children 12 years of age and over:

1 softgel (50mg) at bedtime if needed, or as directed by a doctor

### Other information

store at room temperature 15°-30° C (59°-86° F)

### Inactive ingredients

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

### **Questions or comments?**

Call toll free: 1-855-215-8180

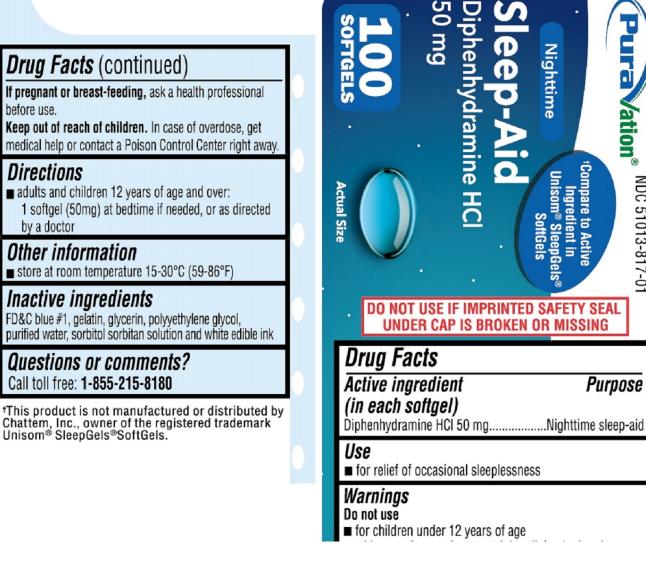
# PRINCIPAL DISPLAY PANEL

Nighttime SLEEP-AID 100 Softgels

Diphenhydramine HCI 50mg

# compare to active ingredient in Unisom<sup>®</sup> SleepGels<sup>®</sup> SoftGels

NDC 51013-817-01



Nighttime

isom® Sleep Ingredient in

SoftGels

Compare to

Active

Purpose

NDC 51013-817-01



	apsule, liquid filled				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:51013-817	
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredient Name Basis of Stren				ength	Strength
DIPHENHYDRAMINE HYDROCHLO (DIPHENHYDRAMINE - UNII:8GTS825	· · · · ·		DIPHENHYDRAMIN HYDROCHLORIDE	E	50 mg
Inactive Ingredients					
	Ingredient Name			St	trength
FD&C BLUE NO. 1 (UNII: H3R47K3	3TBD)				
GLYCERIN (UNII: PDC6A3C0OX)					
GELATIN (UNII: 2G86QN327L)					
SORBITOL (UNII: 506T60A25R)					
WATER (UNII: 059QF0KO0R)					

Pr	roduct Chara	cteristics								
Co	lor	blue (clear blue)	e (clear blue) Score		no score					
Sh	аре	OVAL	Size		13mm					
Fla	avor Imprint Code		PC5							
Co	Contains									
Packaging										
#	Item Code	Package Desc	ription	Marketing Start Date	Marketing End Date					
		100 in 1 BOTTLE; Type 0: No Product	ot a Combination 1	1/30/2024						
Marketing Information										
	Marketing CategoryApplication Number or Monograph Citation			Marketing Start Date	Marketing End Date					
ОТ	C Monograph Drug	g M010		11/30/2024						

Labeler - PuraCap Pharmaceutical LLC (962106329)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(51013-817)

Revised: 11/2024

PuraCap Pharmaceutical LLC