# NIGHTTIME SLEEP-AID- diphenhydramine hcl capsule, liquid filled AMERISOURCE BERGEN

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### **Drug Facts**

### Active ingredient (in each capsule)

Diphenhydramine HCI 50 mg

## Purpose

Nighttime sleep-aid

#### Uses

- for 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

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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 beverages
- 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, consult your doctor. 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 Centre right away.

#### **Directions**

- Adults and children 12 years of age and over: One softgel (50 mg) at bedtime if needed, or as directed by a doctor.
- swallow whole; do not crush, chew, or dissolve

#### Other information

- store at 20°C to 25°C (68°F to 77°F)
- avoid high humidity and excessive heat above 40°C (104°F).
- protect from light

## Inactive ingredients

FD&C blue #1, gelatin, glycerin, hypromellose, lecithin, medium chain triglycerides, polyethylene glycol, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

#### Questions or comments?

call toll free 1-888-235-2466 (Mon - Fri 9AM - 5PM EST)

DO NOT USE IF TAMPER-EVIDENT SEAL UNDER BOTTLE CAP IMPRINTED WITH " SEALED for YOUR PROTECTION" IS BROKEN OR MISSING.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION Made in USA using domestic and imported materials.

<sup>†</sup>This product is not manufactured or distributed by the owners of Unisom <sup>®</sup> SleepGels <sup>®</sup>.

Lot No.:

Exp. Date:

Distributed By AmerisourceBergen 1 West First Ave Conshohocken, PA 19428 Ouestions or Concerns? www.mygnp.com

L0000442

Rev # 04/21

## **60's Count Carton**

GOOD

**NEIGHBOR** 

**PHARMACY®** 

Compare to the active ingredient in Unisom® SleepGels®†

NDC 46122-695-72

Maximum Strength

Nighttime Sleep-aid

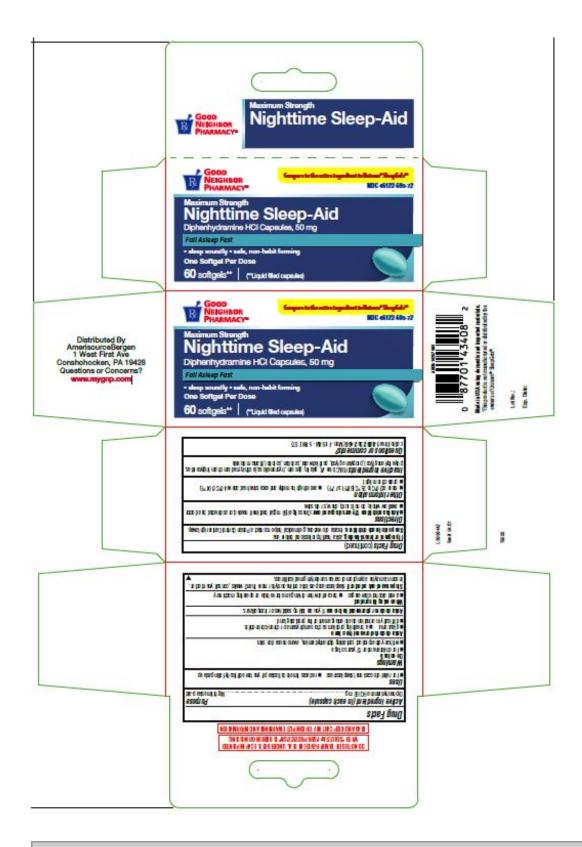
Diphenhydramine HCl Capsules, 50 mg

Fall Asleep Fast

• sleep soundly • safe, non-habit forming

One Softgel Per Dose

60 softgels\*\* I (\*\*Liquid-filled capsules)



## **NIGHTTIME SLEEP-AID**

diphenhydramine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-695
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg	

Inactive Ingredients				
Ingredient Name	Strength			
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
WATER (UNII: 059QF0KO0R)				
SORBITAN (UNII: 6O92ICV9RU)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	P50	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:46122-695- 72	1 in 1 CARTON	07/15/2021		
1		60 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	07/15/2021	

# Labeler - AMERISOURCE BERGEN (007914906)

# Registrant - Bionpharma Inc. (079637826)

Establishment				
Name	Address	ID/FEI	Business Operations	

Patheon Softgels Inc. 002193829 manufacture(46122-695)

Revised: 10/2023 AMERISOURCE BERGEN