

**NIGHTTIME SLEEP-AID- diphenhydramine hcl capsule, liquid filled  
Bionpharma Inc.**

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**Drug Facts**

***Active ingredient (in each capsule)***

Diphenhydramine HCl 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.**

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

Made in USA using domestic and imported materials.

Manufactured for:  
Bionpharma Inc.  
Princeton, NJ 08540

R0223 Lot No.: Exp. Date

L0000704

### **160's count Label**

†Compare to the active ingredient in Unisom<sup>®</sup> SleepGels<sup>®</sup>

NDC 69452-322-79

a+health

maximum strength

nighttime

sleep-aid

diphenhydramine HCl capsules, 50 mg

- fall asleep fast
- sleep soundly
- safe, non-habit forming

160 softgels\*\*

\*\*liquid-filled capsules


one softgel per dose

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<b>Warnings</b> <b>Do not use</b> ■ for children under 12 years of age ■ with any other product containing diphenhydramine, even one used on skin.	
<b>Ask a doctor before use if you have</b> ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ difficulty in urination due to enlargement of the prostate gland	
<b>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</b>	
<b>When using this product</b> ■ avoid alcoholic beverages ■ be careful when driving a motor vehicle or operating machinery	
<b>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.</b>	

L0000704



**N 3 69452 32279 6**

Lot No.:                      Exp. Date:

R0223

PEEL HERE

T00150R0321

<b>Drug Facts (continued)</b> 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.
<b>Directions</b> ■ 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
<b>Other information</b> ■ 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
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## NIGHTTIME SLEEP-AID

diphenhydramine hcl capsule, liquid filled

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69452-322

Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
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			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-322-79	160 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	04/27/2021	

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Patheon Softgels Inc.		002193829	manufacture(69452-322)

Revised: 12/2023

Bionpharma Inc.