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

Diphenhydramine HCI 50mg, Amerisource Bergen, Made in India

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

- \blacksquare glaucoma \blacksquare 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 continuosly 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 Center 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, polyethylene glycol 400, polyethylene glycol 600, propylene glycol, purified water, sorbitol sorbitan solution

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

Distributed By

AmerisourceBergen 1 West First Ave Conshohocken, PA 19428 **Questions or Concerns?**

www.mygnp.com

ABC#: 10287782 Rev: 04/24

Mfg. Lic. No.: TN00002123

Made in India

T00186R0324

L0000797

R0324

Lot No.: Exp. Date:

60's count

Compare to the active ingredient in Unisom® SleepGels®

NDC 46122-775-64

GOOD

NEIGHBOR

PHARMACY

Maximum Strength

Nighttime Sleep-Aid

Diphenhydramine HCI Capsules, USP 50 mg

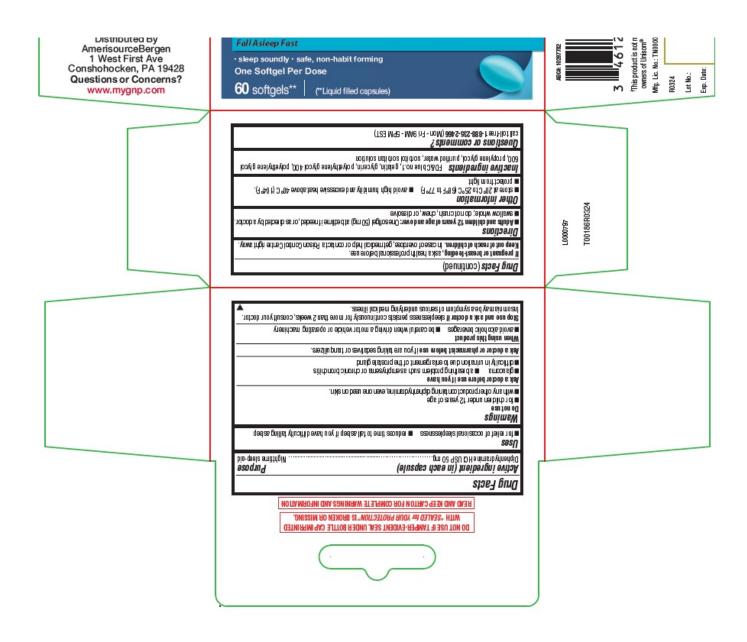
Fall Asleep Fast

• sleep soundly • safe, non-habit forming

One Softgel Per Dose

60 softgels** | (**Liquid-filled capsules)





NIGHTTIME SLEEP-AID

diphenhydramine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-775
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
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	

SORBITAN (UNII: 6092ICV9RU)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	B50	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:46122-775- 64	1 in 1 CARTON	04/11/2024		
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	04/11/2024	

Labeler - AMERISOURCE BERGEN (007914906)

Registrant - Bionpharma Inc. (079637826)

Establishment				
Name	Address	ID/FEI	Business Operations	
SOFTGEL HEALTHCARE PRIVATE LIMITED		675584180	manufacture(46122-775)	

Revised: 4/2024 AMERISOURCE BERGEN