

**NIGHTTIME SLEEP AID- diphenhydramine hcl capsule
TOP CARE (Topco Associates LLC)**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Use

for 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 an 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 a 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 (1-800-222-1222) right away.

Directions

- adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- store between 15-30°C (59°-86°F)

Inactive ingredients

FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, purified water, sorbitol, sorbitan, white ink

Principal Display Panel

COMPARE TO UNISOM® SLEEPGELS® ACTIVE INGREDIENT†

NIGHTTIME SLEEP - AID

DIPHENHYDRAMINE HCl 50 mg • NIGHTTIME SLEEP-AID

- Fall Asleep Fast
- Sleep Soundly
- Wake Up Refreshed
- Non Habit-Forming

SOFTGELS**

**Liquid Filled Capsules

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

**This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepGels®.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

www.topcarebrand.com

Package Label

Drug Facts	
Active ingredient (in each softgel) Diphenhydramine HCl 50 mg.....	Purpose Nighttime sleep-aid
Use For 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 an 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 a 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 (1-800-222-1222) right away.	
Directions ■ adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor	
Other information ■ store between 15-30°C (59-86°F)	
Inactive ingredients FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, purified water, sorbitan, sorbitol, white ink	
Questions or comments? Call toll free 1-888-423-0139	

*This product is not manufactured or distributed by Chatterm, Inc., distributor of Unisom® SleepGels®.



NIGHTTIME

Sleep Aid

DIPHENHYDRAMINE HCl, 50 mg
NIGHTTIME SLEEP-AID

- Fall Asleep Fast
- Sleep Soundly
- Wake Up Refreshed
- Non Habit-Forming

64 SOFTGELS**
**Liquid-Filled Capsules



VALUE PACK

COMPARE TO
UNISOM® SLEEPGELS®
ACTIVE INGREDIENT†

NIGHTTIME

Sleep Aid

DIPHENHYDRAMINE HCl, 50 mg
NIGHTTIME SLEEP-AID

- Fall Asleep Fast
- Sleep Soundly
- Wake Up Refreshed
- Non Habit-Forming

64 SOFTGELS**
**Liquid-Filled Capsules



TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.



Scan here for more information or call 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007
©TOPCO PLVA0521 QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com



This TopCare product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

PLD-H632A F006495

1 BOTTLE INSIDE



Lot No.:
Exp. Date:

TOPCARE HEALTH Nighttime Sleep-Aid

NIGHTTIME SLEEP AID

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-116
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O921CV9RU)	
SORBITOL (UNII: 506T60A25R)	

LIGHT MINERAL OIL (UNII: N6K5787QVP)

MANNITOL (UNII: 3OWL53L36A)

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	PC5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-116-32	1 in 1 BOX	01/31/2020	
1		32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:36800-116-64	1 in 1 BOX	01/31/2020	
2		64 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	01/31/2020	

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 12/2022

TOP CARE (Topco Associates LLC)