

**NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled**  
**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.*

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**Nighttime Sleep Aid**

**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 persist 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 (50 mg) at bedtime if needed, or as directed by a doctor

**Other information**

- Store at 15°-30°C (59°-86°F)

## Inactive ingredients

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

## Questions or comments?

Call toll free: 1-888-423-0139

## PRINCIPAL DISPLAY PANEL - Bottle Label

TopCare Nighttime Sleep Aid

Diphenhydramine HCl 50 mg 96SOFTGELS

NDC 36800-413-96

\*Compare to the active ingredient in Unisom® SleepGels®

**TopCare** health™

NIGHTTIME  
MAXIMUM STRENGTH  
**Sleep Aid**  
DIPHENHYDRAMINE HCl 50 mg • NIGHTTIME SLEEP AID

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

96 SOFTGELS\*\*  
Liquid-Filled Capsules

COMPARE TO UNISOM® SLEEPGELS® ACTIVE INGREDIENT\*

**DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

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a breathing problem such as emphysema or chronic bronchitis  
glaucoma  
trouble urinating due to an enlarged prostate gland

**Drug Facts (continued under label)**  
\*This product is not manufactured or distributed by Chatham, Inc., owner of the registered trademark Unisom® SleepGels® Nighttime Sleep-Aid.  
DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007  
© TOPCO PAPMAG18 QUESTIONS? 1-888-423-0139  
topcare@topco.com www.topcarebrand.com  
MADE IN CHINA  
TOPCO-01

036800423299  
Lot No.:  
Exp. Date:

KEEP HERE

**Drug Facts (continued)**  
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 (50 mg) at bedtime if needed, or as directed by a doctor

**Other information**  
store at room temperature 15°-30°C (59°-86°F) and avoid excessive heat  
do not use if imprinted safety seal under cap is broken or missing

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

**Questions or comments?**  
Call toll free: 1-888-423-0139

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

QUALITY GUARANTEE

## NIGHTTIME SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-413
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)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

**Product Characteristics**

Color	blue (clear)	Score	no score
Shape	capsule (oval)	Size	13mm
Flavor		Imprint Code	PC5
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-413-96	96 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	07/19/2016	

**Labeler** - Topco Associates LLC (006935977)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(36800-413) , analysis(36800-413)