

## **NIGHTTIME SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule Cardinal Health (Leader) 70000**

*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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### **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 right away (1-800-222-1222).

**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**

edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, propylene glycol\*, purified water, sorbitol sorbitan\*

\*contains one or more of these ingredient

**Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

**Principal Display Panel**

COMPARE TO UNISOM® SLEEPGELS® active ingredient†

Sleep Aid

Diphenhydramine HCl, 50 mg | Nighttime Sleep-Aid

For Relief of Occasional Sleeplessness

Non-Habit-Forming

SOFTGELS\*\*

\*\*One Softgel Per Dose

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

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

## Package Label

LEADER<sup>TM</sup>

NDC 70000-0426-1

# Sleep-Aid

Diphenhydramine HCl, 50 mg | Nighttime Sleep-Aid

For Relief of  
Occasional Sleeplessness  
Non-Habit Forming

**32** SOFTGELS\*\*  
\*\*One Softgel Per Dose



Actual Size

**COMPARE TO  
UNISOM<sup>®</sup> SLEEPGELS<sup>®</sup>**  
active ingredient\*

**100% Money Back Guarantee**

CIN 5463872 REV. 3/19



Lot No.:  
Exp. Date:

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

Return to place of purchase if not satisfied.

**100% Money Back Guarantee**  
All LEADER<sup>TM</sup> Brand Products Have A



DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.mylender.com 1-800-200-6313  
Essential to Care<sup>™</sup> since 1979



\*This product is not manufactured or distributed by Chatterm, Inc., distributor of Unisom<sup>®</sup> Sleepgels<sup>®</sup>.  
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## Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

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contains one or more of these ingredients

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

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**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.

**When using this product,** avoid alcoholic drinks.

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers.

**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

**Do not use** ■ in children under 12 years of age ■ with any other product containing diphenhydramine, even one used on skin

## Warnings

**Use** For relief of occasional sleeplessness.

**Active ingredient (in each softgel)** Diphenhydramine HCl 50 mg

**Purpose** Nighttime sleep-aid

LEADER Sleep Aid

NIGHTTIME SLEEP AID    MAXIMUM STRENGTH

diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0426
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)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	P50;A99;D50;AP018
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0426-1	1 in 1 BOX	02/28/2019	12/27/2024
1		32 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	02/28/2019	12/27/2024

Revised: 9/2022

Cardinal Health (Leader) 70000