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.

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**

**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

^{**}One Softgel Per Dose

Package Label

NDC 70000-0426-1

LEADER?

Sleep-Aid

Diphenhydramine HCI, 50 mg | Nighttime Sleep-Aid

For Relief of Occasional Sleeplessness Non-Habit Forming

32 softgels* One Softgel Per Dose



COMPARE TO UNISOM" SLEEPGELS" active ingredient*

100% Money Back Guarantee

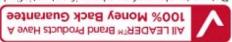


Exp. Date:

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.



Essential to Care" since 1979

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Mightlime sleep-aid

Diphenhydramine HCl 50 mg.

Purpose

Active ingredient (in each softgel)

Drug Facts

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: 6092ICV9RU)			
SORBITOL (UNII: 506T60A25R)			

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

P	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

Labeler - Cardinal Health (Leader) 70000 (063997360)

Revised: 9/2022

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