NIGHTTIME SLEEP AID- diphenhydramine hcl capsule WR Group, Inc.

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 the Active Ingredient in Unisom® SleepGels®

NON HABIT-FORMING

NIGHTTIME

Sleep Aid

Diphenhydramine HCI 50 mg

FALL ASLEEP FAST | SLEEP SOUNDLY

WAKE UP REFRESHED

SOFTGELS**

ONE SOFTGEL PER DOSE

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

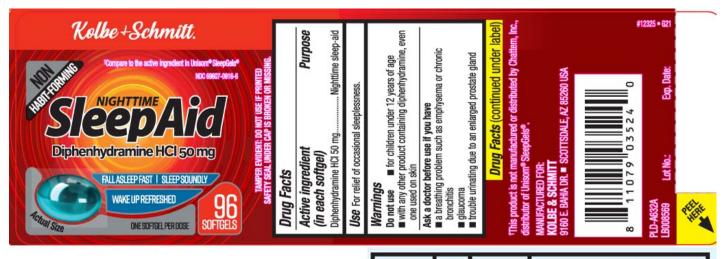
**This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepGels®.

MANUFACTURED FOR:

KOLBE & SCHMITT

9160 E. BAHIA DR. SCOTTSDALE, AZ 85260 USA

Package Label



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KOLBE & SCHMITT Nighttime Sleep Aid

NIGHTTIME SLEEP AID

diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69607-0916
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: 6092ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
MANNITOL (LINII: 30M 53L36A)		

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

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:69607- 0916-6	96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/06/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	08/06/2021	

Labeler - WR Group, Inc. (089173699)

Revised: 4/2024 WR Group, Inc.