

**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 HCl 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



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: 6O92ICV9RU)	
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: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.