#### SLEEP AID- diphenhydramine hcl capsule Family Dollar (FAMILY WELLNESS)

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

- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

# Ask a doctor before use if

- 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

# Questions or comments?

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

# **Principal Display Panel**

COMPARE TO THE ACTIVE INGREDIENT IN UNISOM® SLEEPGELS®\*

Non-Habit Forming

NIGHTTIME SLEEP-AID

Diphenhydramine HCL 50 mg

Help to Reduce Difficulty Falling Asleep

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:**

# MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY

CHESAPEAKE, VA 23320

# Product Label



#### FAMILY WELLNESS Nighttime Sleep Aid

SLEEP AID						
diphenhydramine hcl capsule						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (	Source)	NDC:5531	L9-816	
Route of Administration	ORAL					
· · · · · · · · · ·						
Active Ingredient/Active Moiety						
Ingred	dient Name		Basis of Str	ength	Strength	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)			DIPHENHYDRAMINE HYDROCHLORIDE		50 mg	
In a star In our dis sta						
Inactive Ingredients						
	Ingredient Name			St	trength	
FD&C BLUE NO. 1 (UNII: H3R47K3	TBD)					
GELATIN (UNII: 2G86QN327L)						
GLYCERIN (UNII: PDC6A3C0OX)						
POLYETHYLENE GLYCOL, UNSPE	CIFIED (UNII: 3WJQ0SDW1/	۹)				

WATER (UNII: 059QF0KO0R)					
SORBITAN (UNII: 6092ICV9RU)					
SORBITOL (UNII: 506T60A25R)					
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)					
LIGHT MINERAL OIL (UNII: N6K5787QVP)					
MINERAL OIL (UNII: T5L8T28FGP)					
Product Characteristics					
Color	blue	Score	no	score	

Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	PC5
Contains			

# Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55319- 816-32	1 in 1 BOX	12/27/2019	12/27/2025	
1		32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:55319- 816-64	1 in 1 BOX	12/27/2019	12/27/2025	
2		64 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
Marketing Information					
	Marketing Category	Application Number or Monograph	Marketing Start	Marketing End	

# CategoryCitationDateDateOTC monograph finalpart33812/27/201912/27/2025

Revised: 2/2023

Family Dollar (FAMILY WELLNESS)

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)