# SLEEP AID- diphenhydramine hcl capsule The Kroger Co.

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 HCI 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 at 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

\*may contain this ingredient

#### Questions or comments?

Call **1-800-632-6900** 

## **Principal Display Panel**

# \*\*COMPARE TO the active ingredient in UNISOM® SLEEPGELS® \*\*See back panel

MAXIMUM STRENGTH

Sleep-Aid Softgels

Diphenhydramine HCI, 50 mg

Nighttime Sleep Aid

Safe, Non-Habit Forming

SOFTGELS

ONE SOFTGELS PER DOSE

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

\*\*UNISOM® SLEEPGELS® IS A REGISTERED TRADEMARK OF CHATTEM, INC., CHATTANOOGA, TN 37409. CHATTEM,INC., IS NOT AFFILIATED WITH THE KROGER CO. OR THIS PRODUCT.

#### **DISTRIBUTED BY: THE KROGER CO., CINCINNATI, OHIO 45202**

www.kroger.com

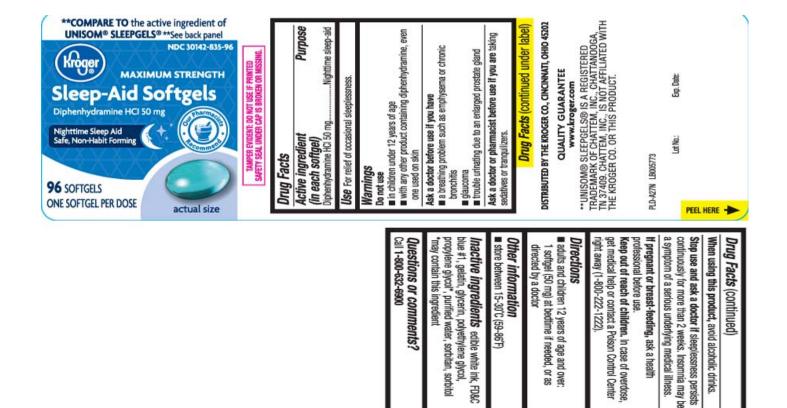
### Package Label

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

GELATIN (UNII: 2G86QN327L) **GLYCERIN** (UNII: PDC6A3C0OX)

WATER (UNII: 059QF0KO0R)



1-800-632-6900

contain this ingredient

-FD&(

## **KROGER Sleep-Aid Softgels**

softgel (50 mg) at bedtime if needed, or as

### **SLEEP AID** diphenhydramine hcl capsule **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:30142-835 **Route of Administration ORAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6|AD40) DIPHENHYDRAMINE 50 mg (DIPHENHYDRAMINE - UNII:8GTS82S83M) **HYDROCHLORIDE Inactive Ingredients Ingredient Name** Strength

SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9O167V3)	

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:30142- 835-96	96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2018	12/27/2024	

Marketing In	arketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part338	04/30/2018	12/27/2024		

# Labeler - The Kroger Co. (006999528)

Revised: 9/2022 The Kroger Co.