## NIGHTTIME SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule Strategic Sourcing Services LLC

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 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, light mineral oil\*, polyethylene glycol, purified water, sorbitol-sorbitan

\*may contain this ingredient

## Questions or comments?

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

## **Principal Display Panel**

Compare to the active ingredient in Unisom® SleepGels®\*\*

MAXIMUM STRENGTH

Nighttime Sleep Aid

## Diphenhydramine HCl, 50 mg

for relief of occasional sleeplessness

Safe, non habit-forming

Softgels

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

**Another Quality Product** 

Distributed by McKesson

One Post Street, San Francisco, CA 94104

www.healthmart.com/healthmartbrand

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

## **Package Label**

Health Mart.

NDC 62011-0226-1

Compare to the active ingredient in Unisom® SleepGels®\*\*

#### MAXIMUM STRENGTH

# Nighttime Sleep Aid

Diphenhydramine HCI, 50 mg

For relief of occasional sleeplessness

Safe, non habit-forming

69

**32** Softgels

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF PRINTED Safety Seal Under Cap is broken or missing.

FC004869 PLD-E27M

healthmart.com Money Back Guarantee One Post Street, San Francisco, CA 94104 Distributed by McKesson Another Quality Product

## **W**ckesson

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

#### Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

may contain this ingredient

purified water, sorbitol-sorbitan

INACTIVE INGICEDIENTS edible white ink, FD&C blue #1, gelatin, glycerin, light mineral oil", polyethylene glycol,

Other information a store between 15-30°C (59-86°F)

■ adults and children 12 years of age and over: 1 softgel (50 mg) at bedfime if needed, or as directed by a doctor Directions

(1-800-555-1555)

Keep out of reach of children, in case of overdose, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use.

serious underlying medical illness.

Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a

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- trouble uninating due to an enlarged prostate gland
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Warnings

USO For relief of occasional sleeplessness.

Vighttime sleep-aid Diphenhydramine HCl 50 mg. Active ingredient (in each softgel) Purpose

Drug Facts

**HEALTH MART Nighttime Sleep Aid** 

diphenhydramine hcl capsule

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0226
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (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)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6 O 9 2 I C V 9 R U )		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	BLUE	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	P50;A99;S90
Contains			

I	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:62011-0226-	1 in 1 BOX	0 2/0 1/20 14	
	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	part341	0 2/0 1/20 14	