NIGHTTIME SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule Care One (Retail Business Services, LLC.)

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®†

Maximum Strength

NIGHTTIME SLEEP - AID

Diphenhydramine HCI 50 mg

Helps to Reduce Difficulty Falling Asleep

SOFTGELS**

**Liquid Filled Capsules

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

DISTRIBUTED BY FOODHOLD U.S.A., LLC LANDOVER, MD 20785

1-877-846-9949

Package Label



water, sorbitan, sorbitol, white ink Inactive ingredients FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, purified OTNET INTORMATION ■ store between 15-30°C (59-86°F) ■ squits and children 12 years of age and over; 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor Directions идиц эмэх Keep out of reach of children. In case of overdose, get medical help or contact a Polson Control Center (1-800-222-1222) If pregnant or breast-reeding, ask a health professional before use. s serious underlying medical illness. Stop use and ask a doctor if sleeplessness persists continuously for more than 2 weeks, insormia may be a symptom of When using this product, avoid alcoholic drinks. Ask a doctor or pharmacist before use it you are taking sedatives or tranquilizers. ■ Bjøncows ■ trouble unnæfing due to an enlarged prostate gland Ask a doctor before use if you have 🔳 a breathing problem such as emphysema or chronic bronchilis with any other product containing diphenhydramine, even one used on skin ■ tor children under 12 years of age esn ton ou *SbujureW* USB For relief of occasional sleeplessness. bis-qasis amittingili Diphenhydramine HCl 50 mg. Purpose Active ingredient (in each soffgel) Drug Facts

CARE ONEMaximum Strength Nighttime Sleep Aid

NIGHTTIME SLEEP AID MAXIMUM STRENGTH

diphenhydramine hcl capsule

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72476-916

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of 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 (UNII: 30WL53L36A)			

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

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:72476- 916-32	1 in 1 BOX	12/27/2019			
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 Drug	M010	12/27/2019			

Labeler - Care One (Retail Business Services, LLC.) (967989935)

Revised: 3/2024 Care One (Retail Business Services, LLC.)