

**NIGHTTIME SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule  
Care One (Retail Business 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 (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 HCl 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**

CAREone™

NDC 72476-916-32  
Compare to the  
Active Ingredient  
in Unisom® SleepGels®†

Maximum Strength

# NIGHTTIME SLEEP - AID

## Diphenhydramine HCl, 50 mg

Helps to Reduce Difficulty Falling Asleep *Actual Size*



### 32 SOFTGELS\*\*

\*\*Liquid Filled Capsules



0120



S-949

Lot No.:  
Exp. Date:

KEEP OUTER CARTON FOR COMPLETE  
WARNINGS AND PRODUCT INFORMATION.

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

PLD-06324  
FC006528

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Quality guaranteed or your money back.

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

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

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■ glaucoma ■ trouble urinating due to an enlarged prostate gland  
■ Ask a doctor before use if you have ■ a breathing problem such as emphysema or chronic bronchitis  
■ 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.

**Use** For relief of occasional sleeplessness.

**Active ingredient (in each softgel)** Diphenhydramine HCl 50 mg. Nighttime sleep-aid

**Purpose**

**Drug Facts**

CARE ONE Maximum Strength Nighttime Sleep Aid

NIGHTTIME SLEEP AID MAXIMUM STRENGTH

diphenhydramine hcl capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-916
<b>Route of Administration</b>	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

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	PC5
<b>Contains</b>			

### 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 FINAL	part338	12/27/2019	

Revised: 3/2020

Care One (Retail Business Services, LLC.)