

**SLEEP AID MAXIMUM STRENGTH- diphenhydramine hcl capsule  
Care One (American Sales Company)**

*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**

- helps to reduce difficulty falling asleep

**Warnings**

**Do not give to children under 12 years of age.**

**Do not use this product**

- With other products containing diphenhydramine, even one used on skin.

**Ask a doctor before use if you have**

- emphysema
- chronic bronchitis
- glaucoma
- difficulty in urination due to an enlargement of the prostate gland

**Ask doctor or pharmacist before use if you are now taking**

sedatives or tranquilizers

**When using this product**

avoid alcoholic beverages

**Stop use and ask a doctor if**

- sleeplessness persists 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.

**Directions**

- **adults and children 12 years of age and over:** take 1 softgel at bedtime if needed or as directed by a doctor

**Other information**

- Store at controlled room temperature 15°-30°C (59°-86°F)
- do not use if imprinted safety seal under cap is broken or missing
- \*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Maximum Strength Unisom SleepGels®

**Inactive ingredients**

edible white ink, FD&C Blue #1, gelatin, glycerin, polyethylene glycol, purified water and sorbitol special.

**Principal Display Panel**

Compare to the Active Ingredient in Maximum Strength Unisom SleepGels®\*

Maximum Strength

Sleep- Aid

Helps to reduce difficulty falling asleep

Diphenhydramine HCl 50 mg

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**Distributed by: American Sales Company**

**4201 walden avenue, Lancaster, NY 14086**

**www.care1.com**

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Quality guaranteed or your money back

**Product Label**

CAREONE®

# SLEEP-AID

**BONUS**  
PACK + 8 Softgels

Compare to the active ingredient in Maximum Strength Unison SleepGels®

CAREONE®

## MAXIMUM STRENGTH SLEEP-AID

Helps to reduce difficulty falling asleep



DIPHENHYDRAMINE HCl 50 mg

32 + 8  
= 40 SOFTGELS

CAREONE®

Compare to the active ingredient in Maximum Strength Unison SleepGels®

CAREONE®

## MAXIMUM STRENGTH SLEEP-AID

Helps to reduce difficulty falling asleep

DIPHENHYDRAMINE HCl 50 mg

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

## MAXIMUM STRENGTH SLEEP-AID

Helps to reduce difficulty falling asleep



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32 + 8  
= 40 SOFTGELS

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PLD-A  
F23C040

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Nighttime sleep-aid

**Purpose**  
Use ■ helps to reduce difficulty falling asleep

**Warnings**  
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Do not use this product with other products containing diphenhydramine, even one used on skin.

Ask a doctor before use if you are now taking sedatives or tranquilizers.

Ask a doctor or pharmacist before use if you are now taking sedatives or tranquilizers.

When using this product avoid alcoholic beverages.

Stop use and ask a doctor if ■ sleepiness persists for more than 2 weeks, insomnia may be a symptom of a serious underlying medical illness.

If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a health professional before use.

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Lot No.:  
Exp. Date:

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Diphenhydramine HCl 50 mg

**SLEEP AID MAXIMUM STRENGTH**

diphenhydramine hcl capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-231
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

**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>	P50;A99
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-231-32	1 in 1 CARTON	07/01/2010	
1		32 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41520-231-40	1 in 1 BOX	07/01/2010	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part341	07/01/2010	

**Labeler** - Care One (American Sales Company) (809183973)**Registrant** - P & L Development, LLC (800014821)