

**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.

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



DIPHENHYDRAMINE HCl 50 mg

32 + 8
= 40 SOFTGELS

DISTRIBUTED BY: American Sales Company
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PLD-A
F23C040

Drug Facts

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

Purpose

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 are now taking sedatives or tranquilizers.

Ask a doctor or pharmacist before use if you are now taking alcohol, caffeine, or other stimulants.

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.

Keep out of reach of children. In case of overdose, get medical help or contact 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.

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 printed safety seal under cap is broken or missing ■ This product is not manufactured or distributed by Chatterm, Inc., owner of the registered trademark Maximum Strength Unison SleepGels®.

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



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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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-231
Route of Administration	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)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-231-32	1 in 1 CARTON		
1		32 in 1 BOTTLE		
2	NDC:41520-231-40	1 in 1 BOX		
2		40 in 1 BOTTLE		

Marketing Information

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

Labeler - Care One (American Sales Company) (809183973)**Registrant** - P and L Development of New York Corporation (800014821)