

**SLEEP AID- 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

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 at 15-30°C (59°-86°F)

Inactive ingredients

edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water, sorbitol, sorbitan*

*contain one or more of these ingredients

Principal Display Panel

Compare to the Active Ingredient in Unisom® SleepGels®†

Maximum Strength

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 Sleep-Aid Softgels

SLEEP AID

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-835
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)	DIPHENHYDRAMINE	50 mg

(DIPHENHYDRAMINE - UNII:8GTS82S83M)

HYDROCHLORIDE

50 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	P50;A99;D50;AP018
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-835-32	1 in 1 BOX	09/30/2018	12/27/2024
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	09/30/2018	12/27/2024

Labeler - Care One (American Sales Company) (809183973)

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