

CAREONE NIGHTTIME SLEEP AID- diphenhydramine hcl capsule, liquid filled
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.

American Sales Company Nighttime Sleep Aid Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Uses

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

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
- difficulty in urination due to an enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- avoid alcoholic beverages

Stop use and ask a doctor if

sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of 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

- take only one dose per day (24 hours)

adults & children 12 yrs & over	2 softgels at bedtime if needed or as directed by a doctor
children under 12 yrs	do not use

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

Inactive ingredients

edible ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredient in Vicks® ZzzQuil® Nighttime Sleep-Aid

NIGHTTIME SLEEP AID

Diphenhydramine HCl Softgels, 25mg

Not For Treating Colds Or The Flu

See Warnings

Non-Habit Forming

Actual Size

Gluten Free

OUR PHARMACISTS RECOMMEND

12 SOFTGELS



Drug Facts (continued)

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

Drug Facts (continued)

Inactive ingredients ed b ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution

Questions or comments? 1-800-71-94260

Drug Facts

Active ingredient (in each softgel)
Diphenhydramine HCl 25mg,Mg HCl time sleep-aid

Uses

- for the relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

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- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
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- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
- When using this product avoid alcoholic beverages.
- 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 breastfeeding, 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

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- adults & children 12 yrs & over
- 2 softgels at bedtime if needed or as directed by a doctor
- do not use

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DO NOT USE IF BUSTER UNIT IS BROKEN OR TORN

*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® ZzzQuil® Nighttime Sleep-Aid.

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NDC 41620-062-63

CAREone™

Compare to the active ingredient
in Vicks® ZzzQuil® Nighttime Sleep-Aid®

NIGHTTIME SLEEP AID

Diphenhydramine HCl Softgels, 25mg

Not For Treating Colds Or The Flu
See Warnings
Non-Habit Forming
Gluten Free

Actual Size

12 SOFTGELS

OUR PHARMACISTS RECOMMEND

CAREONE NIGHTTIME SLEEP AID
diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-052
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	052
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-052-53	6 in 1 CARTON	01/28/2014	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41520-052-62	12 in 1 CARTON	03/24/2014	
2		2 in 1 BLISTER PACK; 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	01/28/2014	

Labeler - American Sales Company (809183973)