

NIGHT TIME SLEEP-AID- diphenhydramine hcl tablet
Advanced Rx LLC

NIGHT TIME SLEEP-AID

Drug Facts

Active ingredients (in each Caplet)

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 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.

Directions

- take only one dose (2 Caplets) per day (24 hours)
-

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

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- read all product information before using
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Inactive ingredients

Microcrystalline Cellulose, Dicalcium Phosphate, Stearic Acid, Croscarmellose Sodium, Colloidal Silicon Dioxide, Hypromellose, Titanium Dioxide, Triacetin, FD&C Red No.40 Lake, FD&C Blue No.2 Aluminum Lake, Polysorbate.

Questions or comments

Call toll free 1-800-630-8895

Monday through Friday 9AM - 5PM EST

Distributed by:

Advanced Rx LLC

1942 NE 163rd St North Miami Beach,
FL 33162 U.S.A.

MADE IN THE USA

PRINCIPAL DISPLAY PANEL

NDC 80513-383-22

Compare to the active ingredient in VICKS[®] ZzzQuil[®] NIGHTTIME SLEEP-AID*

NIGHT TIME SLEEP-AID

Diphenhydramine HCl 25 mg

220 CAPLETS

*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark VICKS[®] ZzzQuil[®] NIGHTTIME SLEEP-AID



Compare to the active ingredient in VICKS®
ZzzQuil® NIGHTTIME SLEEP-AID

NIGHT TIME SLEEP AID

Diphenhydramine HCL 25 mg

25 MG

- ✓ Fast Acting
- ✓ Not-Habit Forming

220
CAPLETS
easy to swallow

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Drug Facts (continued)

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MADE IN THE USA



Lot No.: 4 Exp. Date: 3 80513100093

NIGHT TIME SLEEP-AID

diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-383
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	

Product Characteristics

Color	purple	Score	no score
Shape	CAPSULE (Caplet)	Size	11mm
Flavor		Imprint Code	DPZ
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-383-22	220 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	08/01/2024	

Labeler - Advanced Rx LLC (042795108)

Revised: 8/2024

Advanced Rx LLC