

NIGHTTIME SLEEPAID- diphenhydramine hydrochloride capsule, gelatin coated
Kareway Product, Inc.

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.

Pure-Aid
NIGHTTIME SLEEP-AID

Drug Facts

Active ingredients (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.
- with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products

Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema, or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers or any other sleep-aid

When using this product

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- be careful when driving a motor vehicle or operating machinery

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. Overdose warning: Taking more than directed can cause serious health problems. 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) - see Overdose warning

adults & children 12 yrs & over	One dose = TWO 25 mg Softgels (50 mg) at bed time if needed or as directed by a doctor
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Other information

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

Inactive ingredients

FD&C blue No.1, FD&C Rd No. 40, gelatin, glycerin, polyethylene glycol 400, partially hydrated sorbitol liquid, purified water

Exclusively distributed by:

Kareway Product, Inc.

2550 S. Dominguez Hills Dr.

Compton, CA 90220

Made in Korea

PRINCIPAL DISPLAY PANEL - 12 Capsule Carton



NIGHTTIME SLEEP-AID

diphenhydramine hydrochloride capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 7510-0557
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 in 2

Inactive Ingredients

Ingredient Name	Strength
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
water (UNII: 059QF0K00R)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	SLAD
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0557-1	12 in 1 CARTON		
1		2 in 1 BLISTER PACK		
2	NDC:67510-0557-2	24 in 1 CARTON		
2		2 in 1 BLISTER PACK		
3	NDC:67510-0557-3	36 in 1 CARTON		
3		2 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	10/22/2014	

Labeler - Kareway Product, Inc. (121840057)**Establishment**

Name	Address	ID/FEI	Business Operations
DongKoo Pharm. Ind. Co., Ltd.		688235474	manufacture(67510-0557)