# 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.

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#### 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 sleepaid

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

#### 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

Pure-Aid <sup>™</sup> NightTi Diphenhy	Hyperion as anode underwing meuclemimess.     Hyperion as a service underwing meuclemimess.     Hyperion as a service underwing meuclemimess.     Meep out of reach of children. Overdose warning: Taking     more than directed can cause servicus health problems.     In case of overdose, get medical help or contract a Poison     more than directed can cause servicus health problems.     In case of overdose, get medical help or contract a Poison     more than directed can cause servicus health problems.     In case of overdose, get medical help or contract a Poison     more than directed can cause servicus health problems.     In case of overdose, get medical help or contract a Poison     more than directed can cause servicus health problems.     In teste only one dose per day (24 hours) - see Overdose warning     adults & children         One dose = TVO 25 mg Softgels (50 mg)     adults & cover         20 redose per day (24 hours) - see Overdose warning         adults & control         Control Center right avay.         (1 - 800-222-1222)         adults & control         adults & control         adults & control         advections         advection         advections         advection         advectin         advectin	Warrings Do not use = for children under 12 years of age even one used on skin. even one used on skin. even one used on skin. Mark a doctor before use if you have = a breathing problem suffinistamines and nighttime cold/flu products arch as actima, emphysema, or chronic bronchitis such as asthma, emphysema, or chronic bronchitis fishe a doctor before use if you have = a breathing problem of the prostate gland = heart disease Ask a doctor or pharmacist before use if you are taking of the prostate gland = heart disease factor a doctor or pharmacist before use if you are taking sedatives or tranguliters or any other sleep-aid sedatives or tranguliters or any other sleep-aid	
SLEEP-AID Diphenhydramine HCI	Drug Facts (continued) When using this product a avoid alcoholic beverages and other drugs that cause drowsiness a drowsiness will occur a 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.	Drug Facts Active ingredient (in each softgel) Purpose Diphenhydramine HCI 25 mg	
	Pure-Aid <sup>™</sup> SLEEP-AID LOT & EXP 05570401 & 08/2017	NightTime Diphenhydramine HCI	
	Pure-Aid <sup>™</sup> Night	NDC No. 67510-0557-1 *Compare to ZzzQuil™ LiquiCaps active ingredient*	8 56023 <sup>00557</sup> 3
	NON-HABI (See Warnings) *Not for treating cold or flu	SLEEP-AID iphenhydramine HCI T FORMING SOFTGELS 12 Softgels	Exclusively distributed by: Kareway Product Inc. 2550 S. Dominguez Hills Dr. Compton, CA 90220 Made in Korea
	Drug Facts (continued) Inscrive ingredients FD&C Blue No.1, FD&C Red No. 40, gelain, giycenn, polyethylene glycol 400, parially dehydrated sorbitol liquid, purified water winer of the registered trademark VICKS® Ny0MI®.	Orug Facts (continued)         Other information       = store at 20-25°C (68-77°F)         avoid excessive heat above 40°C (104°F) and high humidity         = protect from light	

### NIGHTTIME SLEEPAID

diphenhydramine hydrochloride capsule, gelatin coated

Product Type     HUMAN OTC DRUG     Item Code (Source)     NDC:67510-0557	Product Information			
	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0557
Route of Administration ORAL	Route of Administration	ORAL		

	Active Moiety				
	Basis of Strength		Strengt		
Diphenhydramine Hydro UNII:8GTS82S83M)	ochloride (UNII: TC2D6JAD40) (Di	Diphenhydramine Hydrochloride		50 mg in 2	
Inactive Ingredients	S				
	Ingredient N	ame		St	rength
FD&C Blue No. 1 (UNII: H	ł3R47K3TBD)				
gelatin (UNII: 2G86QN32	7L)				
glycerin (UNII: PDC6A3C	0OX)				
POLYETHYLENE GLYC	<b>OL 400</b> (UNII: B697894SGQ)				
water (UNII: 059QF0KO0	R)				
FD&C Red No. 40 (UNII: )	WZB9127XOA)				
sorbitol (UNII: 506T60A2	25R)				
<b>Product Characteri</b>	stics				
Color	PURPLE	PURPLE Score		no score	
Shape	CAPSULE	CAPSULE Size		15mm	
	Imprint Code		SLAD		
Flavor		Imprint Code	:	SLAD	
Flavor Contains		Imprint Code		SLAD	
		Imprint Code		SLAD	
		Imprint Code		SLAD	
Contains		Imprint Code	:	SLAD	
Contains Packaging	Package Description				and Date
Contains Packaging # Item Code	Package Description 12 in 1 CARTON			SLAD arketing F	and Date
Contains Packaging # Item Code NDC:67510-0557-1					and Date
Contains Packaging # Item Code 1 NDC:67510-0557-1 1	12 in 1 CARTON				and Date
Contains Packaging # Item Code 1 NDC:67510-0557-1 1	12 in 1 CARTON 2 in 1 BLISTER PACK				and Date
F       Item Code       I       NDC:67510-0557-1       I       I       NDC:67510-0557-2	12 in 1 CARTON2 in 1 BLISTER PACK24 in 1 CARTON				and Date
Fraging         #       Item Code         1       NDC:67510-0557-1         1       NDC:67510-0557-2         2       NDC:67510-0557-2         3       NDC:67510-0557-3	12 in 1 CARTON2 in 1 BLISTER PACK24 in 1 CARTON2 in 1 BLISTER PACK36 in 1 CARTON				and Date
Figure 1       Figure 2       Figure 2 <th< td=""><td><ul> <li>12 in 1 CARTON</li> <li>2 in 1 BLISTER PACK</li> <li>24 in 1 CARTON</li> <li>2 in 1 BLISTER PACK</li> </ul></td><td></td><td></td><td></td><td>and Date</td></th<>	<ul> <li>12 in 1 CARTON</li> <li>2 in 1 BLISTER PACK</li> <li>24 in 1 CARTON</li> <li>2 in 1 BLISTER PACK</li> </ul>				and Date
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## Labeler - Kareway Product, Inc. (121840057)

### Establishment

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