

SLEEP AID- diphenhydramine hcl tablet
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.

Drug Facts

Active ingredient (in each tablet)

Diphenhydramine HCL 25mg

Purpose

Nighttime sleep-aid

Use

helps reduce difficulty falling asleep

Warnings

Do not use

- in 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

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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 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 accidental overdose get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and older

take 2 tablets at bedtime if needed or as directed by your doctor.

Other information

- **each tablet contains:** calcium 0.2mg
- store at room temperature
- avoid excessive heat (greater than 100°F) or humidity

Inactive ingredients

FDC blue #1, microcrystalline cellulose, lactose anhydrous, sodium starch glycolate, corn starch, dicalcium phosphate, stearic acid, silicon dioxide, magnesium stearate, hypromellose, polyethyleneglycol, titanium dioxide, ethanol

Package label

Enter section text here



SLEEP AID

diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0160
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: H3R47K3TBD)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHANETHIOL (UNII: M439R54A1D)	

Product Characteristics

Color	blue	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor		Imprint Code	RM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0160-2	2 in 1 BOX		
1		12 in 1 BLISTER PACK		
2	NDC:67510-0160-0	2 in 1 BOX		
2		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	08/18/2011	

Labeler - Kareway Product, Inc. (121840057)