

SLEEP AID- diphenhydramine hcl tablet
Navarro Discount Pharmacies,LLC

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.

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

FD&C blue no. 2, hydroxypropyl cellulose, hypromellose 2910, lactose anhydrous, microcrystalline cellulose, polyethylene glycol 6000, silicic acid anhydride, sodium starch glycolate, stearic acid, titanium dioxide

Package label

Vida Mia Sleep Aid Original Formula



LOT & EXP.
LOTE & FECHA DE VENCIMIENTO



Tamper Evident Feature: This product is protected in a sealed blister. Do not use if blister or printed foil is broken.
Protección sobre Evidencia de Alteración: Este producto está protegido en una ampolla sellada. No lo use si la ampolla o la lámina de aluminio impresa está rota.

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Diphenhydramine HCl 25mg.....Nighttime sleep-aid</p> <p>Purpose Nighttime sleep-aid</p> <p>Use helps reduce difficulty falling asleep</p> <p>Warnings Do not use ■ in children under 12 years of age ■ with any other product containing diphenhydramine, even one used on skin ■ with other antihistamines</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers</p> <p>When using this product avoid alcoholic beverages</p> <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of accidental overdose get medical help or contact a Poison Control Center right away.</p>	<p>Drug Facts (continued)</p> <p>Directions Adults and children 12 years and older: take 2 tablets at bedtime if needed or as directed by your doctor.</p> <p>Other information ■ each tablet contains: calcium 0.2mg ■ store at room temperature ■ avoid excessive heat (greater than 100°F) or humidity</p> <p>Inactive ingredients FD&C blue no. 2, hydroxypropyl cellulose, hypromellose 2910, lactose anhydrous, microcrystalline cellulose, polyethylene glycol 6000, silicic acid anhydride, sodium starch glycolate, stearic acid, titanium dioxide</p> <p><small>*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare, LP, owner of the registered trademark, Sominex®. *Este producto no es fabricado o distribuido por GlaxoSmithKline Consumer Healthcare, LP, propietario de la marca registrada, Sominex®.</small></p> <p>Exclusively distributed by: Distribuido exclusivamente por: MAGELAN DISTRIBUTION SOLUTIONS Medley, Florida 33178</p> <p> Made in Korea Fabricado en Corea</p>
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SLEEP AID			
diphenhydramine hcl tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:599 70-079
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE -	DIPHENHYDRAMINE	25 mg

UNII:8GTS82S83M)	HYDROCHLORIDE	25 mg
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Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2910 (50 MPA.S) (UNII: 1IVH67816N)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	BD
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59970-079-16	2 in 1 BOX		
1		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	02/01/2013	

Labeler - Navarro Discount Pharmacies,LLC (094930963)

Revised: 2/2013

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