

**SLEEP AID- diphenhydramine hydrochloride 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.*

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**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><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> Diphenhydramine HCl 25mg.....Nighttime sleep-aid</p> <p><b>Purpose</b> Nighttime sleep-aid</p> <p><b>Use</b> helps reduce difficulty falling asleep</p> <p><b>Warnings</b> 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><b>Ask a doctor before use if you have</b> ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland</p> <p><b>Ask a doctor or pharmacist before use if you are taking</b> sedatives or tranquilizers</p> <p><b>When using this product</b> avoid alcoholic beverages</p> <p><b>Stop use and ask a doctor if</b> sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of accidental overdose get medical help or contact a Poison Control Center right away.</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b> <b>Adults and children 12 years and older:</b> take 2 tablets at bedtime if needed or as directed by your doctor.</p> <p><b>Other information</b> ■ each tablet contains: calcium 0.2mg ■ store at room temperature ■ avoid excessive heat (greater than 100°F) or humidity</p> <p><b>Inactive ingredients</b> FD&amp;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><b>Exclusively distributed by:</b> <b>Distribuido exclusivamente por:</b> <b>MAGELAN</b> DISTRIBUTION SOLUTIONS Medley, Florida 33178</p> <p><b>Made in Korea</b> <b>Fabricado en Corea</b></p>
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## SLEEP AID

diphenhydramine hcl tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:59970-079
<b>Route of Administration</b>	ORAL	<b>DEA Schedule</b>	

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

## Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1	
HYDROXYPROPYL CELLULOSE	
MICROCRYSTALLINE WAX	
ANHYDROUS LACTOSE	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
STEARIC ACID	
SILICON DIOXIDE	
HYPROMELLOSE 2910 (50 MPA.S)	
POLYETHYLENE GLYCOL 6000	
TITANIUM DIOXIDE	

## 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

Navarro Discount Pharmacies,LLC