# NIGHTTIME SLEEP AID- diphenhydramine hcl tablet Bi-Mart

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#### **Drug Facts**

#### Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

#### **Purpose**

Nighttime sleep-aid

#### Use

help reduce difficult falling asleep

#### Warnings

#### Do not use

- in children under 12 years of age
- with any other products containing diphenhydramine, even one used on skin
- with other antihistamines

#### Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- 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
- be careful when driveing 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 a 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 (1-800-222-1222) right away.

#### **Directions**

• adults and children 12 years of age and older: take 2 caplets at bedtime if needed or as directed by a doctor

#### Other Information

- each caplet contains:calcium 30 mg
- each caplet contains:phosphorus 15 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture

#### **Inactive Ingredients**

Briliant Blue Lack, Colloidal Silicon Dioxide, Croscarmellose Sodium, Dicalcium Phosphate, Indigo Carmine Lake, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Stearic Acid, Talc, Titanium Dioxide

#### **Questions?**

Call toll-free 1-844-912-4012

Distributed by:

**BI-MART** 

Eugene, OR 97402

PRINCIPAL DISPLAY PANEL



# Facts (continued

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# Ouestions? call toll-free 1-844-912-401 Stearic Acid, Talc, Titanium Dioxide

his product is not manufactured or distributed by the f the registered trademark Sominex\*

Eugene, OR 97402

### NIGHTTIME SLEEP AID

diphenhydramine hcl tablet

Product I	nformation
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HUMAN OTC DRUG Item Code (Source) NDC:37835-812 **Product Type** 

ORAL **Route of Administration** 

#### **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) **DIPHENHYDRAMINE** 25 mg (DIPHENHYDRAMINE - UNII:8GTS82S83M) **HYDROCHLORIDE** 

#### **Inactive Ingredients Ingredient Name** Strength SILICON DIOXIDE (UNII: ETJ7Z6XBU4) CROSCARMELLOSE SODIUM (UNII: M280L1HH48) ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) MAGNESIUM STEARATE (UNII: 70097M6I30)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE ((Caplet))	Size	11mm
Flavor		Imprint Code	S25
Contains			

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:37835-812-	36 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2025	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/01/2025	

# **Labeler -** Bi-Mart (027630078)

## Registrant - Bi-Mart (027630078)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Elysium Pharmaceutical Ltd.		915664486	manufacture(37835-812)	

Revised: 5/2025 Bi-Mart