

SLEEP- diphenhydramine hcl tablet
Salado Sales, 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.

CVP 44-189

Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

helps to 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

- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- drowsiness will occur

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 overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- adults and children 12 years and over: take 2 tablets at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

Other information

- **each tablet contains:** calcium 60 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- protect from moisture
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

Questions or comments?

1-800-426-9391

Principal Display Panel

NIGHTTIME SLEEP AID

**WAKE RESTED
AND REFRESHED**

COMPARE TO
ORIGINAL FORMULA
SOMINEX® ACTIVE
INGREDIENT*

**CVP®
HEALTH**

SLEEP TABLETS

DIPHENHYDRAMINE HCl 25 mg
NIGHTTIME SLEEP AID

16 TABLETS

**WAKE RESTED
AND REFRESHED**

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS
OPENED OR IF BLISTER UNIT IS TORN, BROKEN
OR SHOWS ANY SIGNS OF TAMPERING**

*This product is not manufactured or distributed by Prestige Brands,
Inc., owner of the registered trademark Original Formula Sominex®.
50844 REV0516R18921

Distributed by Salado Sales, Inc., P.O. Box 6115, Temple, Texas 76503
www.CVPproducts.com

NIGHTTIME SLEEP AID

WAKE RESTED AND REFRESHED



COMPARE TO ORIGINAL FORMULA SOMINEX® ACTIVE INGREDIENT*

SLEEP TABLETS

DIPHENHYDRAMINE HCl 25 mg
NIGHTTIME SLEEP AID



HEALTH

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No print/No varnish
Lot & Exp date



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B-0226-189-21-RR
REV0516R18921

Drug Facts (continued)

TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN ■ protect from moisture ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ see end flap for expiration date and lot number

Drug Facts (continued)

Inactive ingredients croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

Questions or comments? 1-800-426-9391

Drug Facts (continued)

Active ingredient (in each tablet) Diphenhydramine HCl 25 mg Nighttime sleep-aid

Purpose Use helps to 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 ■ difficulty in urination due to enlargement of the prostate gland ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers. ■ avoid alcoholic beverages

When using this product

Other information ■ each tablet contains: calcium 60 mg

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Drug Facts (continued)

■ use caution when driving a motor vehicle or operating machinery ■ drowsiness will occur 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.

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A1605R

SLEEP

diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57243-189
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

Product Characteristics

Color	BLUE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;189
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57243-189-21	2 in 1 CARTON	04/10/1990	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	04/10/1990	

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(57243-189)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(57243-189)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(57243-189)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(57243-189)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(57243-189)

Revised: 12/2019

Salado Sales, Inc.