# SLEEP-AID- diphenhydramine hcl tablet ARMY AND AIR FORCE EXCHANGE SERVICE

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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# Exchange Select 44-189

# Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

#### Purpose

Nighttime sleep-aid

#### Uses

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

# **Warnings**

#### Do not use

- for 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
- difficulty in urination due to enlargement of the 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 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 right away.

#### Directions

do not take more than directed

- 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**

exchange√s elect<sup>™</sup>

# Compare to The Active Ingredient of Original Formula Sominex®\*

#### Sleep Aid

Diphenhydramine HCl 25 mg Nighttime Sleep-Aid

Actual Size

# **72 TABLETS**

 $\sqrt{\text{quality value}}$ 

\*This product is not manufactured or distributed by Medtech Products Inc., owner of the registered trademark Original Formula Sominex®.

50844 REV1019K18923

#### "SATISFACTION GUARANTEED OR YOUR MONEY BACK"

Manufactured For Your Military Exchanges Distributed by: LNK International, Inc. Hauppauge, NY 11788 1-800-426-9391

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



Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-189
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDRO CHLO RIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)	

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

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1 NDC:55301-189-23	9 in 1 CARTON	04/10/1990		
1	8 in 1 BLISTER PACK; Type 0: Not a Combination Product			

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

# **Labeler -** ARMY AND AIR FORCE EXCHANGE SERVICE (001695568)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(55301-189)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55301-189)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(55301-189)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	PACK(55301-189)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(55301-189)

Revised: 4/2020 ARMY AND AIR FORCE EXCHANGE SERVICE