# CAREONE NIGHTTIME SLEEP AID- doxylamine succinate tablet American Sales Company

-----

# **American Sales Company Nighttime Sleep Aid Drug Facts**

# Active ingredient (in each tablet)

Doxylamine succinate 25 mg

# **Purpose**

Nighttime sleep-aid

### Use

helps to reduce difficulty in falling asleep

## Warnings

#### Do not use

in children under 12 years of age

### Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

# Ask a doctor or pharmacist before use if you are

taking any other drugs

# When using this product

- avoid alcoholic beverages
- take only at bedtime

# Stop use and ask a doctor if

 sleeplessness persists continuously for more than two 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 overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

### **Directions**

- adults and children 12 years of age and over: take one tablet 30 minutes before going to bed; take once daily or as directed by a doctor
- children under 12 years of age: do not use

### Other information

- store at 68°-77°F (20°-25°C)
- retain in carton until time of use
- see carton end panel for lot number and expiration date

# **Inactive ingredients**

anhydrous dibasic calcium phosphate, dibasic calcium phosphate dihydrate, FD&C blue no. 1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

### Questions or comments?

1-800-719-9260

# **Principal Display Panel**

Compare to the active ingredient in Unisom® SleepTabs®

NIGHTTIME SLEEP AID

Doxylamine Succinate Tablets, 25mg

Nighttime Sleep Aid

Clinically Tested, Proven Effective

One Tablet Per Dose

Gluten Free

Actual Size

OUR PHARMACISTS RECOMMEND

32 TABLETS





#### DO NOTUSE IF BLISTER UNIT IS BROKEN OR TORN. IF DIFFICULT TO OPEN, USE SCISSORS

### **Drug Facts**

#### Active ingredient (in each tablet) Purpose Doxylamine succinate 25 mg......Nighttime sleep-aid

**Use** ■ helps to reduce difficulty in falling asleep

#### Wamings

Do not use in children under 12 years of age

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

- a breathing problem such as asthma, emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland
- Ask a doctor or pharmacist before use if you are taking any other drugs

#### When using this product

■ avoid alcoholic beverages ■ take only at bedtime

#### Stop use and ask a doctor if

■ sleeplessness persists continuously for more than two weeks. Insomnia may be a symptom of serious underlying medical illness.

If pregnant or breast-feeding, ask a health professional

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Centerright away. (1-800-222-1222)

#### Drug Facts (continued)

#### Directions 5 4 1

- adults and children 12 years of age and over: take one tablet 30 minutes before going to bed; take once daily or as directed by a doctor
- children under 12 years of age: do not use

#### Other information

- store at 68°-77°F (20°-25°C)
- retain in carton until time of use
- see carton end panel for lot number and expiration date

Inactive ingredients anhydrous dibasic calcium phosphate, dibasic calcium phosphate dihydrate, FD &C blue no. 1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

#### Questions or comments? 1-800-719-9260

\*This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepTabs®.

DISTRIBUTED BY: FOO DHOLD U.S.A., LLC LAND OVER, MD 20785 · 1-877-846-9949 © 2020 A hold Delhaize Licensing Sàrl Quality guaranteed or your money back.





### CAREONE NIGHTTIME SLEEP AID

doxylamine succinate tablet

### **Product Information**

HUMAN OTC DRUG NDC:41520-634 Product Type Item Code (Source)

ORAL Route of Administration

### Active Ingredient/Active Moiety

**Ingredient Name Basis of Strength** Strength

**DO XYLAMINE SUCCINATE** (UNII: V9 BI9 B5YI2) (DO XYLAMINE - UNII:95QB77JKPL) DOXYLAMINE SUCCINATE 25 mg

### **Inactive Ingredients**

Ingredient Name	Strength
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)	
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	

Product Characteristics					
Color	BLUE	Score	2 pieces		
Shape	OVAL	Size	10 mm		
Flavor		Imprint Code	L441		
Contains					

l	Packaging						
l	#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
ı	1	NDC:41520-634-64	32 in 1 CARTON	05/06/2016			
1	1		1 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		
ANDA	ANDA040167	05/06/2016			

# Labeler - American Sales Company (809183973)

Revised: 7/2020 American Sales Company