# SLEEP AID- doxylamine succinate tablet Walgreen Company

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Walgreens 44-386

### 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
- with any other product containing doxylamine
- unless you have time for a full night's sleep

### 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 any other sleep-aid
- tranquilizers
- any other antihistamines
- any other drugs

# When using this product

- avoid alcoholic beverages
- do not drive a motor vehicle or operate machinery
- 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.

#### **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 controlled room temperature 20°-25°C (68°-77°F)
- see end flap for expiration date and lot number

### Inactive ingredients

dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

#### Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

### Principal display panel

Walgreens

Compare to the active ingredient in Unisom® SleepTabs®††

Sleep Aid DOXYLAMINE SUCCINATE TABLETS, 25 mg / NIGHTTIME SLEEP-AID Nighttime

80 TABLETS

ONE TABLET PER DOSE ACTUAL SIZE

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

†Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands. ††This product is not manufactured or distributed by Chattem, Inc.,

owner of the registered trademark Unisom® SleepTabs®.

DISTRIBUTED BY: WALGREEN CO.
DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
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NDC 0363-0386-31



**WALGREENS 44-386** 

#### **SLEEP AID**

doxylamine succinate tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0386
Route of Administration	ORAL		

# **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) DOXYLAMINE SUCCINATE 25 mg

Inactive Ingredients	
Ingredient Name	Strength
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	blue	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	44;386
Contains			

F	Packaging				
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0363- 0386-31	1 in 1 CARTON	04/05/2024		
1	L	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA040564	04/05/2024			

# Labeler - Walgreen Company (008965063)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(0363-0386)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0363-0386), pack(0363-0386)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0363-0386)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(0363-0386)

Revised: 4/2024 Walgreen Company