

**SLEEP AID- doxylamine succinate tablet**  
**Strategic Sourcing Services LLC**

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**Sunmark 44-386 Delisted**

***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
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

**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 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***

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

### ***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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***

**sunmark®**

\*COMPARE TO UNISOM® SLEEPTABS® ACTIVE INGREDIENT

NDC 70677-0068-1

**sleep aid**

**DOXYLAMINE SUCCINATE 25 mg**

**Nighttime Sleep-Aid**

One tablet per dose

**32 TABLETS**

**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 Chattem, Inc., owner of the registered trademark Unisom® SleepTabs®.

50844 REV1120B38627

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[www.sunmarkbrand.com](http://www.sunmarkbrand.com)

Money Back Guarantee



sunmark®  
sleep aid

sunmark®

\*COMPARE TO UNISOM® SLEEPTABS®  
ACTIVE INGREDIENT  
NDC 70677-0068-1

sleep aid

DOXYLAMINE SUCCINATE 25 mg  
Nighttime Sleep-Aid



ACTUAL  
SIZE

ONE TABLET PER DOSE

32 TABLETS

sunmark®  
sleep aid

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

no print / no varnish area  
lot no. & exp. date



Rev. 06/21

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B-1242-386-27-R  
REV1120838627

**Drug Facts**

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

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

**Warnings**  
Do not use in children under 12 years of age

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■ a breathing problem such as asthma, emphysema or  
■ chronic bronchitis

■ difficulty in urination due to enlargement of the prostate  
gland ■ glaucoma

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any other drugs.

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continuously for more than two 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.

**Drug Facts (continued)**

**Directions**

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

**Other information**

■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS  
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■ 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

\*This product is not manufactured or distributed by Chatham,  
Inc., owner of the registered trademark Unisom® SleepTabs®.  
50844 REV1120838627

## Sunmark 44-386

**SLEEP AID**

doxylamine succinate tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-0068
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	25 mg

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	44;386
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-0068-1	2 in 1 CARTON	04/30/2019	03/15/2025
1		16 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	ANDA040564	04/30/2019	03/15/2025

**Labeler** - Strategic Sourcing Services LLC (116956644)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70677-0068)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70677-0068) , pack(70677-0068)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70677-0068)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70677-0068)

Revised: 10/2023

Strategic Sourcing Services LLC