

**SLEEP AID- doxylamine succinate tablet**  
**Kroger Company**

-----  
**Kroger 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**

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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***

- **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?***

**1-800-632-6900**

***Principal Display Panel***

**COMPARE TO the active ingredient  
of UNISOM® SLEEPTABS®\*See back panel**

NDC 30142-386-27

**Kroger®**

**Nighttime Sleep-Aid**

**OUR PHARMACIST RECOMMENDED**

**Sleep Aid**

Doxylamine Succinate

Tablets, 25 mg

Nighttime Sleep-Aid

actual

size

One Tablet

Per Dose





Kroger 44-386

## SLEEP AID

doxylamine succinate tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30142-386
<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:30142-386-27	2 in 1 CARTON	03/16/2021	
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	03/16/2021	

**Labeler** - Kroger Company (006999528)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(30142-386)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(30142-386) , pack(30142-386)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(30142-386)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(30142-386)