

**SLEEP-AID- doxylamine succinate tablet**  
**Cardinal Health 110, LLC. DBA Leader**

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**Leader 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 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

- 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 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***

**LEADER™**

NDC 70000-0567-1

Sleep-Aid

Doxylamine Succinate Tablets, 25 mg  
Nighttime Sleep-Aid

One Tablet per Dose

**48 TABLETS**

Actual Size

**COMPARE TO  
UNISOM® SLEEPTABS®**

active ingredient\*

100% Money Back Guarantee

**TAMPER EVIDENT: DO NOT USE IF PACKAGE**

**IS OPENED OR IF BLISTER UNIT IS TORN,  
BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

**CIN 5653183 REV. 6/23**

**CardinalHealth™**

DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myleader.com 1-800-200-6313

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All LEADER™ Brand Products Have A

**100% Money Back Guarantee**

Return to place of purchase if not satisfied.

\*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® SleepTabs®.  
50844 REV0123B38622

LEADER<sup>TM</sup>

# Sleep-Aid

Doxylamine Succinate Tablets, 25 mg | Nighttime Sleep-Aid

LEADER<sup>TM</sup>

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# Sleep-Aid

Doxylamine Succinate Tablets, 25 mg | Nighttime Sleep-Aid

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

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DISTRIBUTED BY CARDINAL HEALTH  
DUBLIN, OHIO 43017  
www.myleader.com 1-800-200-6313  
Essential to Care<sup>™</sup> since 1979

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All LEADER<sup>TM</sup> Brand Products Have A  
**100% Money Back Guarantee**

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B-0225-386-22  
REV10123838622

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50844 REV0123838622

**Drug Facts (continued)**

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Doxylamine succinate 25 mg.....Nighttime sleep-aid

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

**Warnings**  
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■ Ask a doctor before use if you have  
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■ bronchitis ■ glaucoma  
■ trouble urinating due to an enlarged prostate gland  
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■ sedatives or any other sleep-aid  
■ tranquilizers  
■ any other antihistamines ■ any other drugs  
■ When using this product  
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■ Stop use and ask a doctor if  
■ sleeplessness persists continuously for more than two weeks.  
■ illness.

**Active ingredient (in each tablet)**  
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by a doctor

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dihydrate, FD&C Blue #1 aluminum lake, magnesium stearate,  
microcrystalline cellulose, sodium starch glycolate

**Questions or comments?**  
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KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

**Leader 44-386**

**SLEEP-AID**

doxylamine succinate tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0567
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (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:70000-0567-1	3 in 1 CARTON	07/23/2020	
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	07/23/2020	

**Labeler** - Cardinal Health 110, LLC. DBA Leader (063997360)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70000-0567)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70000-0567) , pack(70000-0567)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70000-0567)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70000-0567)

Revised: 7/2023

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