

SLEEP AID NIGHTTIME- doxylamine succinate tablet
Cardinal Health

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

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

- take only at bedtime
- avoid alcoholic beverages

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 (1-800-222-1222) right away.

Directions

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

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

dicalcium phosphate, 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 70000-0249-1

Sleep Aid

Doxylamine Succinate, 25 mg 1 Nighttime Sleep-Aid

Fall Asleep Fast

One Tablet Per Dose

Easy to Swallow

32 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 5315494 REV. 2/17

CardinalHealth™

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

Essential to Care™ since 1979

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All LEADER™ Brand Products Have A

100% Money Back Guarantee

Return to place of purchase if not satisfied.

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50844 ORG051338627

LEADER²

Sleep Aid

Doxylamine Succinate, 25 mg | Nighttime Sleep-Aid

NDC 70000-0249-1

LEADER²LEADER²

Sleep Aid

Doxylamine Succinate, 25 mg | Nighttime Sleep-Aid

Fall Asleep Fast
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32 TABLETS



ACTUAL SIZE

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UNISOM[®] SLEEPTABS[®]
active ingredient*

100% Money
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Sleep Aid

Doxylamine Succinate, 25 mg | Nighttime 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



CIN 5315494

REV. 2/17

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50844 086051338627

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8:30 AM-4:00 PM ET, Monday-Friday

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microcrystalline cellulose, sodium starch glycolate

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Drug Facts (continued)

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KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

B-0225-386-27-R
086051338627

SLEEP AID NIGHTTIME

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0249
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

Product Characteristics

Color	BLUE	Score	2 pieces
Shape	OVAL	Size	10 mm
Flavor		Imprint Code	44;386
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0249-1	2 in 1 CARTON	04/11/2002	02/03/2023
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	04/11/2002	02/03/2023

Labeler - Cardinal Health (097537435)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(70000-0249)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(70000-0249)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(70000-0249)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(70000-0249)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(70000-0249)