

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

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 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

- **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™

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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.

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

50844 REV0123B38622

LEADERTM

Sleep-Aid

Doxylamine Succinate Tablets, 25 mg | Nighttime Sleep-Aid

LEADERTM

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

LEADERTM

Sleep-Aid

Doxylamine Succinate Tablets, 25 mg | Nighttime Sleep-Aid

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

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



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DUBLIN, OHIO 43017
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Essential to Care[™] since 1979

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100% Money Back Guarantee

Return to place of purchase if not satisfied.

B-0225-386-22
REV10123838622

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50844 REV0123838622

Drug Facts (continued)

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Ask a doctor or pharmacist before use if you are taking
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■ any other antihistamines ■ any other drugs
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KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Leader 44-386

SLEEP-AID

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0567
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			

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: 7/2024

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