

NIGHTTIME SLEEP AID- doxylamine succinate tablet
CVS PHARMACY

CVS 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 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

♥CVSHealth®

Compare to the active ingredient
in Unisom® SleepTabs®*

Tablets

Nighttime

Sleep-Aid

DOXYLAMINE SUCCINATE TABLETS, 25 mg

Nighttime Sleep-Aid

Helps to reduce difficulty
in falling asleep

Actual Size

48 TABLETS

One tablet per dose

**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 REV0123A38622

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KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

<p>Drug Facts Active ingredient (in each tablet) Doxylamine succinate 25 mgNighttime sleep-aid</p>	<p>Use ■ helps to reduce difficulty in falling asleep</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are taking ■ sedatives or any other sleep-aid ■ tranquilizers ■ any other antihistamines ■ any other drugs</p> <p>When using this product ■ avoid alcoholic beverages ■ do not drive a motor vehicle or operate machinery ■ take only at bedtime</p> <p>Stop use and ask a doctor if ■ sleepiness persists continuously for more than two weeks, insomnia may be a symptom of serious underlying medical illness.</p>
<p>Drug Facts (continued) 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.</p> <p>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</p> <p>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</p> <p>Inactive ingredients FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate</p> <p>Questions or comments? Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday</p>	<p>Distributed by: CVS Pharmacy, Inc. © 2022 CVS/pharmacy One CVS Drive, Woonsocket, RI 02895 CVS.com® 1-800-SHOP CVS V-11112</p> <p>TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING</p>

B-4231-386-22-HR
REV0123A38622

CVSHealth. Tablets

Nighttime Sleep-Aid
DOXYLAMINE SUCCINATE TABLETS, 25 mg

Compare to the active ingredient in Unisom® SleepTabs®
Tablets

CVSHealth.

Nighttime Sleep-Aid
DOXYLAMINE SUCCINATE TABLETS, 25 mg

CVSHealth.

Nighttime Sleep-Aid
DOXYLAMINE SUCCINATE TABLETS, 25 mg
Nighttime Sleep-Aid
Helps to reduce difficulty in falling asleep



Actual Size



Lot/Expiry



CVS 44-386

NIGHTTIME SLEEP AID

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-386
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (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:69842-386-22	3 in 1 CARTON	07/20/2019	
1		16 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-386-96	2 in 1 CARTON	07/20/2019	

2	96 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040564	07/20/2019	

Labeler - CVS PHARMACY (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(69842-386)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(69842-386) , pack(69842-386)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(69842-386)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(69842-386)

Revised: 8/2023

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