NIGHTTIME SLEEP AID- doxylamine succinate tablet Better Living Brands, LLC

Signature Care 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

Signature

care®

Quality Guaranteed

COMPARE TO

Unisom® SleepTabs® active ingredient*

NDC 21130-986-27

Nighttime Sleep Aid

DOXYLAMINE SUCCINATE TABLETS, 25 mg Nighttime Sleep-Aid

One tablet per dose

Actual Size

32 TABLETS

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., distributors of Unisom® SleepTabs®. 50844 REV0123F38627

DISTRIBUTED BY: BETTER LIVING BRANDS LLC P.O. BOX 99, PLEASANTON, CA 94566-0009 \$1-888-723-3929

LOVE IT



OR IT'S ON US‡

#1-888-723-3929 PO. BOX 99, PLEASANTON, CA 94566-0009 DISTRIBUTED BY: BETTER LIVING BRANDS LLC

FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline

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Questions or comments?

cellulose, sodium starch glycolate

20844 REV0123F38627 Chattem, Inc., distributors of Unisom® SleepTabs®. *This product is not manufactured or distributed by

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■ do not drive a motor vehicle or operate machinery When using this product a avoid alcoholic beverages

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■ trouble unnating due to an enlarged prostate gland Ask a doctor before use if you have

a breathing problem

> ■ nujess you have time for a full night's sleep ■ with any other product containing doxylamine Do not use I in children under 12 years of age Mamings

OS6 - pelps to reduce difficulty in falling saleep

Vighttime sleep-aid

Doxylamine succinate 25 mg. Active ingredient (in each tablet)

Drug Facts

COMPARE TO

Unisom® Sleep Tabs® active ingredient*

Keep out of reach of children. In case of overdose, get medical

Purpose If pregnant or breast-feeding, ask a health professional before

Orug Facts (continued)

Directions

Nighttime Sleep Aid





Quality Guaranteed



Nighttime Sleep Aid

DOXYLAMINE SUCCINATE TABLETS. 25 mg

Nighttime Sleep-Aid

Actual Size

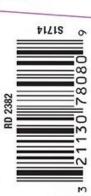


32 TABLETS



Nighttime Sleep Aid

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 print/No varnish Lot & Exp date 9

Signature Care 44-386

NIGHTTIME SLEEP AID

doxylamine succinate tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-986

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: 5856 3G2A2)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	10mm	
Flavor		Imprint Code	44;386	
Contains				

l	Packaging						
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:21130- 986-27	2 in 1 CARTON	07/15/2019			
	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	07/15/2019		

Labeler - Better Living Brands, LLC (009137209)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(21130-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(21130-986) , pack(21130-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(21130-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(21130-986)

Revised: 7/2023 Better Living Brands, LLC