## SLEEP AID- doxylamine succinate tablet Rite Aid Corporation

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Rite Aid 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
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

#### Ask a doctor or pharmacist before use if you are

taking any other drugs.

#### When using this product

- avoid alcoholic beverages
- 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 (1-800-222-1222) 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

RITE AID PHARMACY®

\*Compare to the active ingredient in Unisom® SleepTabs®

sleep aid doxylamine succinate 25 mg nighttime sleep aid

helps to reduce difficulty falling asleep

just one tablet per dose

easy to swallow

actual size easy to swallow

#### **48 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., owner of the registered trademark Unisom® SleepTabs®.

50844 REV0718B38622

DISTRIBUTED BY: RITE AID 30 HUNTER LANE CAMP HILL, PA 17011

SATISFACTION GUARANTEED IF YOUR'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY.

## sleep aid

doxylamine succinate 25 mg

nighttime sleep aid

nighttime sleep aid

Sleep aid

in Unisom® SleepTabs®

\*Compare to the active ingredient



RITE

AID

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ITEM 0348943

Lot no/Exp date

# sleep aid

doxylamine succinate 25 mg

nighttime sleep aid



actual size easy to swallow

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CAMP HILL, PA 17011

30 НОИТЕР LANE

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sleep aid

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NSG pelbs to reduce difficulty in falling asleep

Nighttime sleep-aid Doxylamine succinate 25 mg. (in each tablet) Active ingredient

Drug Facts

Purpose

directed by a doctor

Drug Facts (continued)

B-1702-386-22-R REV0718B38622

TINVALIE DISTRIBUTED BY: RITE AID

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

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

Unestions or comments? Call 1-800-426-9391

stearate, microcrystalline cellulose, sodium starch dihydrate, FD&C blue #1 aluminum lake, magnesium Inactive ingredients dibasic calcium phosphate

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- store at controlled room temperature 20°-25°C (68°-77°F)
  - OPENED OR BLISTER IS TORN OR BROKEN
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS Other information

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

children under 12 years: do not use

minutes before going to bed; take once daily or as adults and children 12 years and over: take one tablet 30

Directions

#### **SLEEP AID**

doxylamine succinate tablet

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-9386

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	25 mg

### **Inactive Ingredients**

inactive ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9 EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

#### **Product Characteristics**

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

#### Packaging

П	1 4611481118			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1 NDC:11822-9386-2	3 in 1 CARTON	07/30/2019	
l	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	07/30/2019	

#### **Labeler -** Rite Aid Corporation (014578892)

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Establishillent			
Name	Address	ID/FEI	Business Operations

MANUFACTURE(11822-9386)
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INK	International.	Inc
LINIX	milernational.	шіс.

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Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11822-9386)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	PACK(11822-9386)

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			
LNK International, Inc.		967626305	PACK(11822-9386)			

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		868734088	PACK(11822-9386)		

Revised: 5/2020 Rite Aid Corporation