

SLEEP AID- doxylamine succinate tablet
Rite Aid Corporation

Rite Aid 44-386 Delisted

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

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 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

NDC 11822-9386-6

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

SLEEP-AID

DOXYLAMINE SUCCINATE 25 mg

nighttime sleep-aid

helps to reduce difficulty 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 REV1120C38622

DISTRIBUTED BY: RITE AID

30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

SATISFACTION GUARANTEED
If you're not satisfied, we'll
happily refund your money.





Rite Aid 44-386

SLEEP AID doxylamine succinate tablet				
Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		ORAL	NDC:11822-9386	
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:11822-9386-2	3 in 1 CARTON	07/30/2019	09/21/2024
1		16 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11822-9386-6	1 in 1 CARTON	07/30/2019	09/21/2024
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	07/30/2019	09/21/2024

Labeler - Rite Aid Corporation (014578892)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(11822-9386) , pack(11822-9386)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(11822-9386)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(11822-9386)

Revised: 7/2023

Rite Aid Corporation