

SLEEP AID- doxylamine succinate tablet
Walgreen Company

Walgreens 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
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

taking

- any other drugs
- sedatives or any other sleep-aid
- any other antihistamines
- tranquilizers

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

- 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

VALUE SIZE

Walgreens

WALGREENS PHARMACIST RECOMMENDED†

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

**Sleep Aid
DOXYLAMINE SUCCINATE TABLETS,
25 mg / NIGHTTIME SLEEP-AID
Nighttime**

**80
TABLETS**

ONE TABLET PER DOSE

ACTUAL SIZE

**TAMPER EVIDENT: DO NOT USE IF
IMPRINTED SAFETY SEAL UNDER CAP IS
BROKEN OR MISSING**

†Our pharmacists recommend the Walgreens brand. We invite you to compare to national brands.

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

DISTRIBUTED BY: **WALGREEN CO.**

DEERFIELD, IL 60015

100% SATISFACTION GUARANTEED

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50844 ORG012338631

NDC 0363-0386-31



WALGREENS 44-386

SLEEP AID

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0386
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	25 mg
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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:0363-0386-22	3 in 1 CARTON	04/05/2024	
1		16 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-0386-31	1 in 1 CARTON	04/05/2024	
2		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:0363-0386-12	1 in 1 CARTON	12/31/2024	
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040564	04/05/2024	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(0363-0386)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0363-0386) , pack(0363-0386)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(0363-0386)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0363-0386)