TOPCARE SLEEP AID- doxylamine succinate tablet Topco Associates LLC

Topco Associates LLC. Sleep Aid Tablets Drug Facts

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
- glaucoma
- trouble urinating due to an enlarged prostate gland

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 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. (1-800-222-1222)

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 68°-77°F (20°-25°C)
- retain in carton until time of use
- see carton end panel for lot number and expiration date

Inactive ingredients

anhydrous dibasic calcium phosphate, dibasic calcium phosphate dihydrate, FD&C blue no. 1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare_® health

COMPARE TO UNISOM® SLEEPTABS® ACTIVE INGREDIENT

NIGHTTIME

Sleep Aid

DOXYLAMINE SUCCINATE TABLETS, 25 mg

NIGHTTIME SLEEP-AID

- Clinically Tested, Proven Effective
- One Tablet Per Dose

32 TABLETS

actual size

*This product is not manufactured or distributed by **LKEE** GLUTEN CE

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TOPCO ASSOCIATES LLC Y8 @TU8MT2IQ

1-888-423-0139

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Your total satisfaction is guaranteed. rested to guarantee its nignest quality. This TopCare® product is laboratory

Chattem, Inc., distributor of Unisom ® SleepTabs®

(1-800-225-1222)

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 - chronic bronchitis

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call 1-888-423-0139 information or Scan here for more



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Drug Facts (continued)

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CONVENIENT RECLOSING



TOPCARE SLEEP AID

doxylamine succinate tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-441

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	
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)		
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
ED&C RUIE NO. 1 (UNII: H3R47K3TRD)		

Product Characteristics							
Color	BLUE	Score	no score				
Shape	OVAL	Size	10mm				
Flavor		Imprint Code	L441				
Contains							

ı	Packaging					
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
]	NDC:36800-441- 64	32 in 1 CARTON	01/29/1997			
]	L	1 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	ANDA040167	01/29/1997				

Labeler - Topco Associates LLC (006935977)

Revised: 1/2023 Topco Associates LLC