

TOPCARE SLEEP AID- doxylamine succinate tablet
Topco Associates LLC

Topco Associates LLC. Sleep Aid 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
- 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
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking

- a sedative 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 (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 20-25°C (68-77°F)
- keep carton. It contains important information.

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

Package/Label Principal Display Panel

TopCare® health

COMPARE TO VICKS® ZZZQUIL® ULTRA ACTIVE INGREDIENT

NIGHTTIME

Sleep Aid

ULTRA

DOXYLAMINE SUCCINATE TABLETS, 25 mg

NIGHTTIME SLEEP-AID

Clinically Tested, Proven Effective

24 TABLETS

actual size

1 Tablet Dose



96F62 88 C2

OPEN OTHER END

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN. IF DIFFICULT TO OPEN, USE SCISSORS.

Drug Facts	Drug Facts (continued)
<p>Active ingredient (in each tablet) Doxylamine succinate 25 mg.....Nighttime sleep-aid</p> <p>Purpose</p> <p>Use ■ helps to reduce difficulty in falling asleep</p> <p>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</p> <p>Ask a doctor before use if you have ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland</p> <p>Ask a doctor or pharmacist before use if you are taking ■ a sedative or any other sleep-aid ■ tranquilizers ■ any other antihistamines ■ any other drugs</p> <p>When using this product ■ avoid alcoholic beverages ■ do not drive a motor vehicle or operate machinery ■ take only at bedtime</p>	<p>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.</p> <p>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).</p> <p>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</p> <p>Other information ■ store at 20-25°C (68-77°F) ■ keep carton. It contains important information.</p> <p>Inactive ingredients anhydrous dibasic calcium phosphate, dibasic calcium phosphate dihydrate, FD&C blue no. 1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate</p> <p>Questions or comments? 1-888-423-0139</p>

CONVENIENT RECLOSING TAB

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

TOPCARE SLEEP AID

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-159
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

Product Characteristics

Color	BLUE	Score	2 pieces
Shape	OVAL	Size	10mm
Flavor		Imprint Code	L441
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-159-62	24 in 1 CARTON	06/16/2023	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:76162-159-67	48 in 1 CARTON	01/24/2024	
2		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	06/16/2023	

Labeler - Topco Associates LLC (006935977)

Revised: 3/2024

Topco Associates LLC