

SOUND BODY NIGHTTIME SLEEP AID- doxylamine succinate tablet
Big Lots Stores, Inc.

Big Lots, Inc Nighttime 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

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?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Unisom[®] SleepTabs[®]

Doxylamine Succinate Tablets, 25 mg

Nighttime Sleep-Aid

Clinically Tested, Proven Effective

32 TABLETS

One Tablet Per Dose

Actual Size



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Nighttime Sleep-Aid



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SOUND BODY NIGHTTIME SLEEP AID

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50594-441
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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

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:50594-441-64	32 in 1 CARTON	04/24/2019	
1		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	04/24/2019	

Labeler - Big Lots Stores, Inc. (017885351)

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Big Lots Stores, Inc.