

NIGHTTIME SLEEP AID- nighttime sleep aid tablet
Allegiant Health

439 - Nighttime Sleep Aid

Active ingredient(s)

Doxylamine succinate 25 mg

Purpose

Nighttime sleep-aid

Use(s)

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 emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to an enlargement of the 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 2 weeks.
Insomnia may be a symptom of a serious underlying medical illness.

If pregnant or breastfeeding,

ask a health professional before use.

Keep out of reach of children

Overdose Warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 of age: do not use

Other information

- DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
- store at controlled room temperature 20°- 25°C (68°- 77°F)
- use by expiration date on package

Inactive ingredients

dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions

Call 1-888-952-0050 Monday through Friday 9AM - 5PM

Principal Display Panel



Drug Facts
Active ingredient (in each tablet) Purpose Doxylamine succinate 25 mgNighttime sleep-aid
Uses 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 emphysema or chronic bronchitis ■ glaucoma ■ difficulty in urination due to an enlargement of the 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
Drug Facts (continued on inside)
<small>*This product is not manufactured or distributed by Chatterm, Inc., owner of the registered trademark Unisom® SleepTabs®. Distributed by: Allegiant Health LE2095 R1222</small>

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Nighttime sleep aid

NIGHTTIME SLEEP AID

nighttime sleep aid tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-439
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
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:69168-439-06	120 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2023	
2	NDC:69168-439-84	2 in 1 CARTON	05/16/2023	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69168-439-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	11/06/2023	
4	NDC:69168-439-98	200 in 1 BOTTLE; Type 0: Not a Combination Product	11/06/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040564	05/16/2023	

Labeler - Allegiant Health (079501930)

Revised: 3/2023

Allegiant Health