NIGHTTIME SLEEP AID- nighttime sleep aid tablet Family Dollar Stores, Inc

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

- 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 blister unit is broken or torn
- 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/Comments

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

Principal Display Panel



NIGHTTIME SLEEP AID

nighttime sleep aid tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-439

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		
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: 585613G2A2)			

Product Characteristics					
Color	blue	Score	no score		
Shape	OVAL	Size	10mm		
Flavor		Imprint Code	44;386		
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55319-439- 16	2 in 1 CARTON	10/31/2023			
1		8 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	ANDA040564	10/31/2023		

Labeler - Family Dollar Stores, Inc (024472631)

Revised: 7/2023 Family Dollar Stores, Inc