

NOCTO SLEEP AID- doxylamine succinate tablet
Belmora LLC

Nocto 44-386

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
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

taking

- sedatives 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.

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 controlled room temperature 20°-25°C (68°-77°F)
- see end flap for expiration date and lot number

Inactive ingredients

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

Questions or comments?

Call 1-888-779-2877 M-F 9AM-5PM EST

Principal display panel

Belmora LLC

NDC 27854-375-01

NOCTO®

SLEEP AID

Doxylamine Succinate Tablets 25 mg

Nighttime Sleep-Aid

Helps to reduce
difficulty in falling asleep

24 Tablets

Actual Size

One Tablet Per Dose

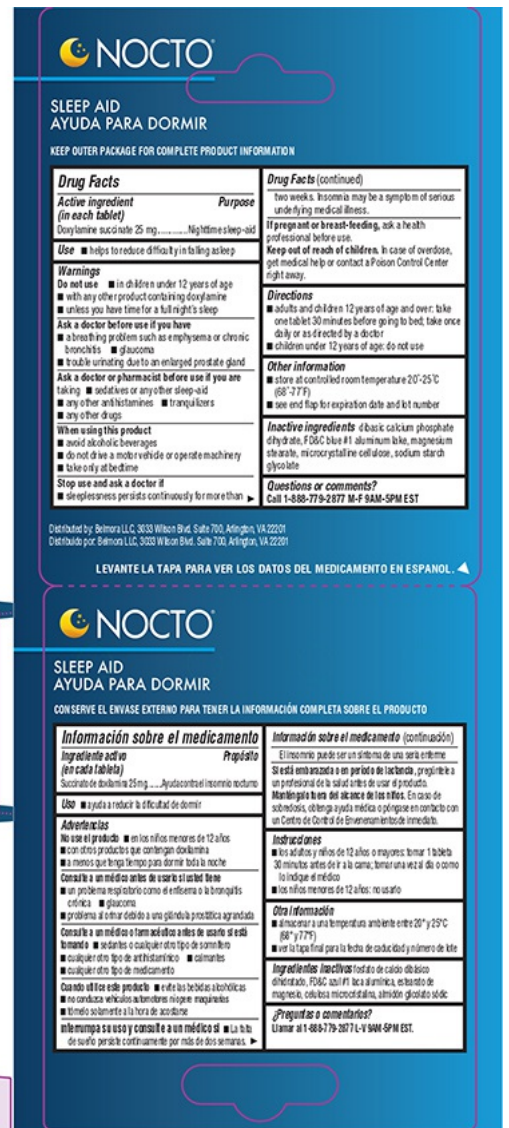
**TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

NOT TO BE SOLD IF PACKAGE IS TORN OR MISSING DOSAGE INFORMATION.

Distributed by: Belmora LLC, 3033 Wilson Blvd. Suite 700, Arlington, VA 22201



Nocto 44-386



NOCTO SLEEP AID

doxylamine succinate tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:27854-375

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:27854-375-01	1 in 1 CARTON	10/31/2019	
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA040564	10/31/2019		

Labeler - Belmora LLC (112753244)

Revised: 7/2024

Belmora LLC