

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 asthma, emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the 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

24 Tablets

Actual Size

**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.

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Nocto 44-386

**SLEEP AID
AYUDA PARA DORMIR**

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts	Purpose	Drug Facts (continued)
Active ingredient (in each tablet): Doxylamine succinate 25 mg	Nighttime sleep-aid	two weeks. Insomnia may be a symptom of serious underlying medical illness.
Use: ■ helps to reduce difficulty in falling asleep		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.
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		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
Ask a doctor or pharmacist before use if you are taking: ■ sedatives or any other sleep-aid ■ any other antihistamines ■ tranquilizers ■ any other drugs		Other information: ■ store at controlled room temperature 20°-25°C (68°-77°F) ■ see end flap for expiration date and lot number
When using this product: ■ avoid alcoholic beverages ■ do not drive a motor vehicle or operate machinery ■ take only at bedtime Skip use and ask a doctor if: ■ sleeplessness persists continuously for more than		Inactive ingredients: dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate
		Questions or comments? Call 1-888-776-2877 M-F 9AM-5PM EST

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Distribuido por Belterra LLC, 3033 Wilson Blvd., Suite 700, Arlington, VA 22201

LEVANTE LA TAPA PARA VER LOS DATOS DEL MEDICAMENTO EN ESPAÑOL. ▶

**SLEEP AID
AYUDA PARA DORMIR**

CONSERVE EL ENVASE EXTERNO PARA TENER LA INFORMACIÓN COMPLETA SOBRE EL PRODUCTO

Información sobre el medicamento	Propósito	Información sobre el medicamento (continuación)
Ingrediente activo (en cada tableta): Succinato de doxilamina 25 mg	Ayuda contra el insomnio nocturno	El insomnio puede ser un síntoma de una seria enfermedad.
Uso: ■ ayuda a reducir la dificultad de dormir		Si está embarazada o en período de lactancia, pregúntele a un profesional de la salud antes de usar el producto. Manténgalo fuera del alcance de los niños. En caso de sobredosis, obtenga ayuda médica o póngase en contacto con un Centro de Control de Envenenamientos Inmediato.
Advertencias: No use el producto: ■ en los niños menores de 12 años ■ con otros productos que contengan doxilamina ■ a menos que tenga tiempo para dormir toda la noche Consulte a un médico antes de usarlo si usted tiene: ■ un problema respiratorio como el asma o la bronquitis crónica ■ glaucoma ■ problema al orinar debido a una glándula prostática agrandada		Instrucciones: ■ los adultos y niños de 12 años o mayores: tomar 2 tabletas 30 minutos antes de ir a la cama; tomar una vez al día o como lo indique el médico ■ los niños menores de 12 años: no usarlo
Consulte a un médico o farmacéutico antes de usarlo si está tomando: ■ sedantes o cualquier otro tipo de somnífero ■ cualquier otro tipo de antihistamínico ■ calmantes ■ cualquier otro tipo de medicamento		Otra información: ■ almacenar a una temperatura ambiente entre 20° y 25°C (68° y 77°F) ■ ver la tapa final para la fecha de caducidad y número de lote
Consulte al médico antes de usarlo: ■ en los días de alcoholismo ■ si recada en actividades que requieran maquinaria ■ si toma solamente a la hora de acostarse		Ingredientes (incluido el colorante de calcio dihidrógeno, FD&C azul #1 azul aluminio, estearato de magnesio, celulosa microcristalina, almidón glicolato sódico)
Interrompa su uso y consulte a un médico si: ■ la falta de sueño persiste continuamente por más de dos semanas.		¿Preguntas o comentarios? Llámanos al 1-888-776-2877 L-V 9AM-5PM EST

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)