

NIGHTTIME SLEEP AID- doxylamine succinate tablet
Amerisource Bergen

Good Neighbor Pharmacy 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
- glaucoma
- trouble urinating due to an enlarged prostate gland

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

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal display panel

**Good
Neighbor
Pharmacy®**

***Compare to the active ingredient
in Unisom® SleepTabs®**

NDC 46122-788-15

Nighttime Sleep Aid

Doxylamine succinate tablets 25 mg

Nighttime Sleep-Aid

- **One tablet per dose**

32 tablets

Actual Size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Chattem,
Inc., owner of the registered trademark Unisom® SleepTabs®.
50844 ORG012338627

Distributed By
AmerisourceBergen
1 West First Avenue
Conshohocken, PA 19428
Questions or Concerns?
www.mygnp.com



Nighttime Sleep Aid

Doxylamine succinate tablets 25 mg



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no print / no varnish area
lot no. & exp. date

ABC#: 10288251 Rev: 04/24



3 46122 78815 1



Distributed By
AmersourceBergen
1 West First Avenue
Conshohocken, PA 19428
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B-0045-306-27
ORG012338627

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts	Drug Facts (continued)
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 ■ sedatives or any other sleep-aid ■ tranquilizers ■ any other anti-stimulants ■ 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.	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 Ask a doctor before use if you have ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN ■ store at controlled room temperature 20°-25°C (68°-77°F) ■ see end flap for expiration date and lot number	Inactive ingredients basic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate
Questions or comments? Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday	50844 ORG012338627

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Good Neighbor 44-386

NIGHTTIME SLEEP AID

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-788
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (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:46122-788-15	2 in 1 CARTON	06/07/2024	
1		16 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	06/07/2024	

Labeler - Amerisource Bergen (007914906)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(46122-788)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(46122-788) , pack(46122-788)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(46122-788)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(46122-788)

Revised: 6/2024

Amerisource Bergen