NIGHTTIME SLEEP AID- doxylamine succinate tablet
L.N.K. International, Inc.

Quality Plus 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

QUALITY
+PLUS

NDC 50844-386-19

*Compare to active ingredient in
Unisom® SleepTabs®

NIGHTTIME
SLEEP AID

Doxylamine succinate tablets, 25 mg

Nighttime Sleep-Aid

One Tablet Per Dose

8
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 REV0123B38619

Distributed by **LNK INTERNATIONAL, INC.**
60 Arkay Drive, Hauppauge, NY 11788
USA


KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION
Drug Facts
Active ingredient (in each tablet)
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50844 REV0123B3861 9
Distributed by LNK INTERNATIONAL, INC.
60 Arkay Drive, Hauppauge, NY 11788
USA
QUALITY PLUS NIGHTTIME SLEEP AID
8 Tablets
B-1603-386-19
REV0123B38619
QUALITY PLUS NIGHTTIME SLEEP AID
QUALITY PLUS
NDC 50844-386-19
*Compare to active ingredient in Unisom® SleepTabs®
NIGHTTIME SLEEP AID
Doxylamine succinate tablets, 25 mg
Nighttime Sleep-Aid
8 Tablets
One Tablet Per Dose
ACTUAL SIZE
TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING
No print/No varnish Lot & Exp date
3 50844 38619 9

Quality Plus 44-386

NIGHTTIME SLEEP AID

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-386
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: 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:50844-386-19	1 in 1 CARTON	04/11/2002	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50844-386-90	32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/11/2002	
3	NDC:50844-386-27	2 in 1 CARTON	04/11/2002	
3		16 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:50844-386-22	3 in 1 CARTON	04/11/2002	
4		16 in 1 BLISTER PACK; Type 0: Not a Combination Product		

5	NDC:50844-386-96	2 in 1 CARTON	04/11/2002	
5		96 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	04/11/2002	

Labeler - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(50844-386)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(50844-386) , pack(50844-386)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(50844-386)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(50844-386)

Revised: 3/2024 L.N.K. International, Inc.