SLEEP AID- doxylamine succinate tablet ARMY AND AIR FORCE EXCHANGE SERVICE

Exchange Select 44-386

Active ingredient (in each tablet)

Doxylamine succinate 25 mg

Purpose

Nighttime sleep-aid

Use

helps to reduce difficulty in falling asleep

Warnings

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 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 two weeks. Insomnia may be a symptom of a 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 (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: 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

Compare To The Active Ingredient of Unisom® SleepTabs®*

Sleep Aid

Doxylamine succinate 25 mg

Nighttime Sleep-Aid

32 TABLETS

Actual Size

- For a restful sleep
- Easy to swallow
- One tablet per dose

"SATISFACTION GUARANTEED OR YOUR MONEY BACK"

Manufactured For Your Military Exchanges Distributed by: LNK International, Inc., Hauppauge, NY 11788 1-800-426-9391

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® SleepTabs®. 50844 REV0718A38627

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





stearate, microcrystalline cellulose, sodium starch glycolate

dihydrate, FD&C blue #1 aluminum lake, magnesium INACTIVE INGREDIEMS dibasic calcium phosphate

■ see end flap for expiration date and lot number TYT-'89) J'25-'02 eiture ature 20'-25'C (68'-77'F) OPENED OR BLISTER IS TORN OR BROKEN

■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS Uther information

■ children under 12 years: do not use daily or as directed by a doctor take one tablet 30 minutes before going to bed; take once Directions

a adults and children 12 years and over:

(1-800-222-1222) right away. medical help or contact a Poison Control Center Keep out of reach of children. In case of overdose, get before use. If pregnant or breast-feeding, ask a health professional

Drug Facts (continued)

fake only at bedfime ■ avoid alcoholic beverages

When using this product

any other drugs.

Ask a doctor or pharmacist before use if you are taking

gland ■ glaucoma

 difficulty in unination due to enlargement of the prostate chronic bronchitis

■ a breathing problem such as astrima, emphysema or Aska doctor before use if you have Warnings

USe helps to reduce difficulty in falling asleep

Doxylamine succinate 25 mg. Nighttime sleep-aid

(in each tablet)

Purpose Active ingredient

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Exchange Select 44-386

SLEEP AID

doxylamine succinate tablet

doxyminine succurate tubict			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-986
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

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

Packaging					
# Item Code Package Description	Marketing Start Date	Marketing End Date			
1 NDC:55301-986-27 2 in 1 CARTON	0 4/0 1/20 19				
16 in 1 BLISTER PACK; Type 0: Not a Combination Pro	duct				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA040564	0 4/0 1/20 19			

Labeler - ARMY AND AIR FORCE EXCHANGE SERVICE (001695568)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55301-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(55301-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(55301-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(55301-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(55301-986)

Revised: 1/2020 ARMY AND AIR FORCE EXCHANGE SERVICE