

SLEEP AID- doxylamine succinate tablet
FRED'S, INC.

Freds Pharmacy 44-386-Bisect-delisted

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

- glaucoma
- a breathing problem such as asthma, emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

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: take one tablet 30 minutes before going to bed; take once daily or as directed by a doctor
- do not give to children under 12 years of age

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

dicalcium phosphate, 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

**fred's
Pharmacy**

NDC 55315-986-27

Compare to the active ingredient in: Unisom[®] SleepTabs[®]*

Sleep Aid

Doxylamine succinate, 25 mg

Nighttime Sleep-Aid

Fall Asleep Fast / Safe

Easy to Swallow

Actual Bottle Size on Side Panel

Package Contains One Bottle

32 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**

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

50844 REV0513E38627

**DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD, MEMPHIS, TN 38118
www.fredsinc.com**

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient *Purpose*
(in each tablet)
Doxylamine succinate 25 mg. Nighttime sleep-aid

Use helps to reduce difficulty in falling asleep

Warnings

Ask a doctor before use if you have
■ glaucoma
■ a breathing problem such as asthma, emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

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.

Drug Facts (continued)

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

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 dicalcium phosphate, 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

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® SleepTabs®. 50844 REV0513E38627

100% satisfaction guaranteed
Questions or comments: 1-855-331-FRED (3733)

DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD, MEMPHIS, TN 38118
www.fredsinc.com

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

B-0510-386-27-R
REV0513E38627

fred's Pharmacy

Sleep Aid

32 TABLETS
ONE TABLET PER DOSE

Compare to the active ingredient in Unisom® SleepTabs®

32 TABLETS
ONE TABLET PER DOSE

Doxylamine succinate, 25 mg

Nighttime Sleep-Aid

Fall Asleep Fast / Safe

Easy to Swallow

Sleep Aid

fred's Pharmacy

ACTUAL SIZE

NDC 55315-986-27

32 TABLETS
ONE TABLET PER DOSE

Doxylamine succinate, 25 mg

Nighttime Sleep-Aid

Compare to the active ingredient in Unisom® SleepTabs®

0 84579 10044 6

No Print / No Varnish
Lot no. & Exp. date

SLEEP AID

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-986
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

Product Characteristics

Color	BLUE	Score	2 pieces
Shape	OVAL	Size	10mm
Flavor		Imprint Code	44;386
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-986-27	2 in 1 CARTON	04/11/2002	04/30/2022
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	04/11/2002	04/30/2022

Labeler - FRED'S, INC. (005866116)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(55315-986)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(55315-986)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(55315-986)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(55315-986)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(55315-986)

Revised: 9/2019

FRED'S, INC.