

SLEEP AID- doxylamine succinate tablet
Wal-Mart Stores Inc

Equate 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

- glaucoma
- a breathing problem such as asthma, emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the 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

- store at controlled room temperature 20°-25°C (68°-77°F)
- use by expiration date on package

Inactive ingredients

dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

1-888-287-1915

Principal display panel

equate™

NDC 49035-968-27

Compare to

Unisom®

SleepTabs®

active

ingredient*

Sleep-Aid

Doxylamine succinate 25 mg

Nighttime Sleep-Aid

- One Tablet Per Dose

Actual Size

32

TABLETS

**TAMPER EVIDENT: DO NOT USE IF
IMPRINTED SAFETY SEAL UNDER CAP
IS BROKEN OR MISSING**

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® SleepTabs®. 50844 REV0123B38627

Equate 44-386

doxylamine succinate tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-968
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:49035-968-27	32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040564	07/15/2019	

Labeler - Wal-Mart Stores Inc (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(49035-968)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(49035-968) , pack(49035-968)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(49035-968)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(49035-968)