## SLEEP AID- doxylamine succinate tablet Wal-Mart Stores Inc

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**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<sup>™</sup>

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** 

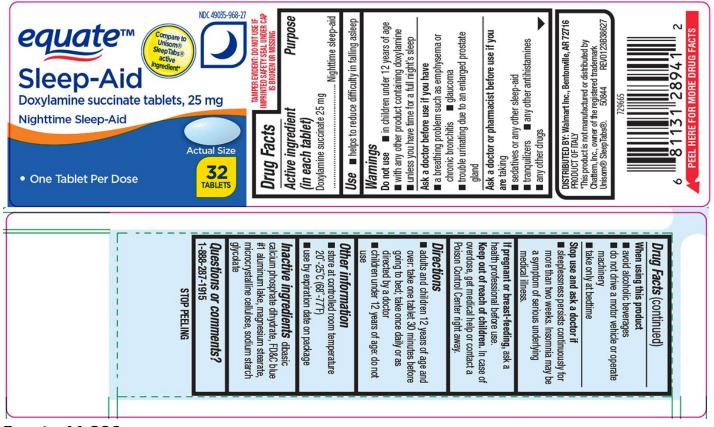
#### 32 TABLETS

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

#### **DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716**

PRODUCT OF ITALY

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



**Equate 44-386** 

#### **SLEEP AID**

doxylamine succinate tablet

<b>Product Information</b>			
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	
<b>1</b> 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	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(49035-968)

<b>Establishment</b>			
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)

Revised: 5/2025 Wal-Mart Stores Inc