

**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 emphysema or chronic bronchitis
- 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***

- 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**

**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®.

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REV0123B38627

**Equate 44-386**

<b>SLEEP AID</b>			
doxylamine succinate tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49035-968
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)		DOXYLAMINE SUCCINATE	25 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			

<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	44;386
<b>Contains</b>			

### 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.		117025878	manufacture(49035-968)