

UNISOM SLEEPTABS- doxylamine succinate tablet
Chattem, Inc.

Unisom Sleep Tabs-2

Drug Facts

Active ingredient (in each tablet)

Doxylamine succinate 25 mg

Purpose

Nighttime sleep-aid

Use

- helps to reduce difficulty in falling asleep

Warnings

See carton for complete 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

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- 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

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

■ **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
- 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?

1-866-844-2798 Monday - Friday 8am-6pm ET

Principal Display Panel

**Unisom
SleepTabs**

**Doxylamine succinate tablets, 25 mg
NIGHTTIME SLEEP-AID**

Unisom[®] SleepTabs[®]
Doxylamine succinate tablets, 25 mg
NIGHTTIME SLEEP-AID

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Doxylamine succinate tablets, 25 mg
NIGHTTIME SLEEP-AID

Unisom[®]

SleepTabs[®]  Clinically Tested,
Proven Effective^{*}

**Doxylamine succinate tablets, 25 mg
NIGHTTIME SLEEP-AID**

 ACTUAL SIZE

4
Tablets
One Tablet per dose

Certified  Distributed by: Chatten, Inc.,
P.O. Box 2219, Chattanooga, TN 37409-0219
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0166594-01

 **PAPER BOX** **MULTI-LAYER TRAY**

Tablet includes a generic inert fill.
*Active Ingredient Doxylamine Succinate  Clinically Tested, Proven Effective.

9C-010-961-4
BUD

0 41167 06084 1

373-077

Drug Facts (continued)

Drug Facts
Doxylamine succinate 25 mg.....(Doxylamine succinate)

Active ingredient (in each tablet)

Purpose
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
■ when you have been given a full night's sleep

Use
■ Ask a doctor before use if you have
■ a breathing problem such as emphysema or chronic
■ bronchitis ■ asthma
■ trouble urinating due to an enlarged prostate gland
■ Ask a doctor or pharmacist before use if you are taking
■ medicine or any other sleep-aid ■ tranquilizers
■ any other medications ■ 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
■ drowsiness persists continuously for more than two weeks.
■ You may be a symptom of another underlying medical
■ illness.

Other information
■ Adults and children 12 years of age and over: Take one
■ tablet 30 minutes before going to bed, then once daily or as
■ directed by a doctor
■ Children under 12 years of age: Do not use

Directions
■ Adults and children 12 years of age and over: Take one
■ tablet 30 minutes before going to bed, then once daily or as
■ directed by a doctor

Keep out of reach of children. In case of overdose, get
■ medical help or contact a Poison Control Center right away.

Drug Facts (continued)
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, then once daily or as
■ directed by a doctor

Other information
■ Ask a doctor before use if you have
■ a breathing problem such as emphysema or chronic
■ bronchitis ■ asthma
■ trouble urinating due to an enlarged prostate gland
■ Ask a doctor or pharmacist before use if you are taking
■ medicine or any other sleep-aid ■ tranquilizers
■ any other medications ■ 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
■ drowsiness persists continuously for more than two weeks.
■ You may be a symptom of another underlying medical
■ illness.

Questions or comments?
Call 1-800-846-2798 Monday - Friday, 9am-5pm ET
Visit www.unisom.com

Active ingredients
■ Doxylamine succinate (Doxylamine succinate) 25 mg (0.45 mmol)
■ Inert ingredients: hydroxypropyl methylcellulose, hydroxypropyl
■ methylcellulose, croscarmellose sodium, polyethylene glycol, sodium
■ starch, polyethylene glycol, polyethylene glycol, polyethylene glycol, polyethylene glycol

Contains 4 tablets.

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

UNISOM SLEEPTABS

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0608
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	25 mg

Inactive Ingredients

Ingredient Name	Strength
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	blue (Light Blue)	Score	2 pieces
Shape	OVAL	Size	13mm
Flavor		Imprint Code	Unisom;ST
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0608-4	1 in 1 CARTON	03/16/2026	
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-0608-0	1 in 1 CARTON	03/16/2026	
2		16 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41167-0608-1	1 in 1 CARTON	03/16/2026	
3		32 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:41167-0608-2	1 in 1 CARTON	03/16/2026	
4		48 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:41167-0608-3	1 in 1 CARTON	03/16/2026	
		96 in 1 BOTTLE; Type 0: Not a Combination Product		

5	80 in 1 BOTTLE; Type O: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040564	03/16/2026	

Labeler - Chattem, Inc. (003336013)

Revised: 3/2026

Chattem, Inc.