

UNISOM SLEEPTABS- doxylamine succinate tablet
Chattem, Inc.

Unisom SleepTabs

Unisom® SleepTabs®

Doxylamine succinate tablets Nighttime Sleep-Aid

Drug Facts

Active ingredient (in each tablet)

Doxylamine succinate 25 mg

Purpose

Nighttime sleep-aid

Uses

- 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

- 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

- sedative 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. (1-800-222-1222)

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 20° to 25°C (68 °-77 °F)
- Keep carton. It contains important information

Inactive ingredients

anhydrous dibasic calcium phosphate, dibasic calcium phosphate dihydrate, FD&C blue no. 1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments: 1-866-844-2798 Monday- Friday 8am-6pm EST

PRINCIPAL DISPLAY PANEL

Unisom Sleeptabs
Doxylamine succinate
25 mg

Nighttime Sleep-Aid
32 Tablets



UNISOM SLEEPTABS
doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0063
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
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	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:41167-0063-5	1 in 1 CARTON	01/15/2016	
1		16 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-0063-6	1 in 1 CARTON	01/15/2016	
2		32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:41167-0063-7	1 in 1 CARTON	01/15/2016	
3		48 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:41167-0063-8	1 in 1 CARTON	01/15/2016	
4		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040167	01/15/2016	

Labeler - Chattem, Inc. (003336013)

Revised: 4/2023

Chattem, Inc.