

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

Ask a doctor before use if you have

- a breathing problem such as asthma, emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking any other drugs

When using this product

- avoid alcoholic beverages
- 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 68° to 77°F (20° to 25°C)
- retain in carton until time of use

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

PRINCIPAL DISPLAY PANEL

Unisom SleepTabs
Doxylamine succinate
25 mg

Nighttime Sleep-Aid
80 Tablets

80 ct. VALUE SIZE

Now in a Bottle!

Unisom®

SleepTabs®

Doxylamine succinate tablets, 25 mg

Clinically Tested,
Proven Effective

NIGHTTIME SLEEP-AID



ACTUAL SIZE

80 Tablets

One Tablet per dose

05127/CC1

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CHATTEM®
A SANOFI COMPANY

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Unisom®

SleepTabs®

Doxylamine succinate tablets, 25 mg
NIGHTTIME SLEEP-AID

Drug Facts (continued)

Directions
Adults and children 12 years of age and over: take one tablet 30 minutes before going to bed; take once daily as directed by a doctor.
Children under 12 years of age: do not use.

Other Information
Store at 68°-77°F (20°-25°C). Keep in original container until time of use.

Inactive Ingredients anhydrous ethanol, calcium phosphate, dibasic calcium phosphate dihydrate, FD&C Blue No. 1, aluminum lactate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

Questions or comments? 1-800-833-1818



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LOT NO.

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Drug Facts (continued)

Warnings
Do not use in children under 12 years of age.
Ask a doctor before use if you have:
a breathing problem such as asthma, emphysema or chronic bronchitis
glaucoma
trouble urinating due to an enlarged prostate gland
Ask a doctor or pharmacist before use if you are taking any other drugs.
When using this product: avoid alcoholic beverages; take only at bedtime.
Stop use and ask a doctor if:
drowsiness persists continuously for more than two weeks; symptoms may be a symptom of serious underlying medical condition.
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)



Drug Facts

Active ingredient (in each tablet)
Doxylamine succinate 25 mg

Purpose
Nighttime sleep-aid

Use
Helps to reduce difficulty in falling asleep

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

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: LM26O6933) | |
| 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: 5/2018

Chattem, Inc.