

CAREONE NIGHTTIME SLEEP AID- doxylamine succinate tablet
American Sales Company

American Sales Company Nighttime Sleep Aid Drug Facts

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

- 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

- a 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°-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?

1-800-719-9260

Principal Display Panel

CAREone®

Compare to the active ingredient in Unisom® SleepTabs®

NIGHTTIME SLEEP AID

Doxylamine Succinate Tablets, 25mg

Nighttime Sleep Aid

Clinically Tested, Proven Effective

One Tablet Per Dose

Gluten Free

Actual Size

32 TABLETS

This product is not manufactured or distributed by Chattem, Inc., a Sanofi Company, distributor of Unisom® SleepTabs®, DISTRIBUTED BY: ADUSA DISTRIBUTION, LLC, SAUS BURY, NC 28147
 For product questions or concerns, contact us at 1-833-992-3872
 Quality guaranteed or your money back.



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 one tablet 30 minutes before going to bed; take once
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Other information
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 keep cardboard in its original container for information.

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

Questions or comments? 1-800-719-9260

Drug Facts (continued)
 Stop use and ask a doctor if
 sleeplessness persists continuously for more than
 two weeks. Insomnia may be a symptom of a 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).

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN. IF DIFFICULT TO OPEN, USE SCISSORS.

44164 OF C3

CAREone®

NIGHTTIME SLEEP AID

Doxylamine Succinate Tablets, 25mg

Nighttime Sleep Aid

CAREone®

NDC 41520-634-64

Compare to the active ingredient
 in Unisom® SleepTabs®*

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Doxylamine Succinate Tablets, 25mg

Nighttime Sleep Aid
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 One Tablet Per Dose
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Actual Size



32 TABLETS



CAREONE NIGHTTIME SLEEP AID

doxylamine succinate tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41520-634 |
| 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 |
|---|----------|
| ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) | |
| 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 (UNII: H8AV0SQX4D) | |

Product Characteristics

| | | | |
|-----------------|------|---------------------|----------|
| Color | BLUE | Score | 2 pieces |
| Shape | OVAL | Size | 10mm |
| Flavor | | Imprint Code | L441 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:41520-634-64 | 32 in 1 CARTON | 05/06/2016 | |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA040167 | 05/06/2016 | |

Labeler - American Sales Company (809183973)

Revised: 4/2025

American Sales Company