SLEEP AID- doxylamine succinate tablet CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED

CVS 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

- 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 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

Inactive ingredients

dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal display panel

♥CVS™

NDC 51316-368-22

actual size

SLEEP-AID

Doxylamine Succinate Tablets, 25 mg Nighttime Sleep-Aid

Compare to Unisom® SleepTabs® active ingredient*

Helps to reduce difficulty in falling asleep

48 TABLETS

(ONE TABLET PER DOSE)

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

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® SleepTabs®.

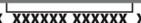
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 Insomnia may be a symptom of serious underlying medical
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 - do not drive a motor vehicle or operate machinery
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When using this product

- any other antihistamines any other drugs
- Ask a doctor or pharmacist before use if you are taking setatives or any other sleep-aid setanguilizers

 - Ask a doctor before use if you have a breathing problem such as emphysema or chronic
 - Do not use in children under 12 years of age ■ with any other product containing doxylamine ■ unless you have time for atull right's sleep
 - spnimsW

USC In helps to reduce difficulty in falling asleep

Doxylamine succinate 25 mg......Mghttime sleep-aid

Active ingredient Purpose (in each tablet)

Drug Facts

3.

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Questions or comments?

starch glycolate

Inactive ingredients
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- see end flap for expiration date and lot number
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use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Conbol Center right away.

Drug Facts (continued)
If pregnant or breast-feeding, ask a health professional before

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

CVS

SLEEP-AID

48 TABLETS
(ONE TABLET PER DOSE)

NDC 51316-368-22





actual size

SLEEP-AID

Doxylamine Succinate Tablets, 25 mg Nighttime Sleep-Aid

Compare to Unisom® SleepTabs® active ingredient*

Helps to reduce difficulty in falling asleep

48 TABLETS

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SLEEP AID

doxylamine succinate tablet

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51316-368

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

| induite ingredients | | | | |
|--|----------|--|--|--|
| Ingredient Name | Strength | | | |
| 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 POTATO (UNII: 5856J3G2A2) | | | | |
| | | | | |

| Product Characteristics | | | |
|-------------------------|------|--------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL | Size | 10mm |
| Flavor | | Imprint Code | 44;386 |
| Contains | | | |

| P | Packaging | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:51316- 368-22 | 3 in 1 CARTON | 06/25/2025 | | | |
| 1 | | 16 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 | ANDA040564 | 06/25/2025 | | |
| | | | | |

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

| Establishment | | | |
|-------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 038154464 | pack(51316-368) |

| Establishment | | | |
|-------------------------|---------|-----------|---|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 832867837 | manufacture(51316-368), pack(51316-368) |

| Establishment | | | | |
|-------------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| LNK International, Inc. | | 967626305 | pack(51316-368) | |

| Establishment | | | |
|-------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 117025878 | manufacture(51316-368) |

Revised: 6/2025 CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED