## GOOD SENSE SLEEP AID- doxylamine succinate tablet L. Perrigo Company

-----

#### Perrigo Sleep Aid Tablets 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

#### 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°-77°F (20°-25°C)
- retain in carton until time of use
- see carton end panel for lot number and expiration date

#### **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**

Nighttime

Sleep Aid Tablets

Doxylamine Succinate Tablets, 25 mg

Nighttime Sleep-Aid

Actual Size

Clinically Tested, Proven Effective

One Tablet Per Dose

Compare to active ingredient of Unisom® SleepTabs®

100% SATISFACTION GUARNATEED

32 Tablets

(1-800-SSS-1SSS)

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

If pregnant or breast-feeding, ask a health professional

nuqeulying medical liness.

- two weeks. Insomnia may be a symptom of serious ■ sleeplessness persists confinuously for more than
  - Stop use and ask a doctor if
- take only at bedtime ■ gvoid alcoholic beverages When using this product

tak ing any other drugs

Ask a doctor or pharmacist before use if you are

- trouble unimating due to an enlanged prostate gland ■ glaucoma
  - chronic bronchilis
- a breathing problem such as as three, emphysema or Ask a doctor before use ifyou have

Do n of use in children under 12 years of age sbui me W

■ helps to reduce difficulty in falling asleep

Do xylamine succinate 25 mg............Ni ghtti me sleep-aid Active ingredient (in each tablet) Purpose

Story Burd

O TO 64 IM , nagell A



Va betudinted By

Gluten Free

Muestions of comments? 1-800-719-9260

microcrystalline cellulose, sodium starch glycolate ASC blue no. 1 aluminum lake, magnesium stearate, buosbyste, dbasic calcium prosphate dihy drate, INSCINE IN Gred lents anhydrous dibasic calcium

- zee certou end panel for lot number and expiration date ■ retain in carton until time of use ■ store at 68°-77°F (20°-25°C) Other information
- children under 12 years of age: do not use or as directed by a doctor tablet 30 minutes before going to bed; take once daily squits and children 12 years of age and over: take one Directions

Drug Facts (continued)

TO OPEN, USE SCIS SORS BROKEN OR TORN, IF DIFFICULT DO NOT USE IF BLISTER UNIT IS

## GOODSENSE.

Sleep Aid Tablets Doxylamine Succinate Tablets, 25 mg Nighttime Sleep-Aid

# GOODSENSE.

NDC 0113-0441-64

**Nighttime** 

# Sleep Aid Tablets

Doxylamine Succinate Tablets, 25 mg Nighttime Sleep-Aid

- Clinically Tested, Proven Effective
- One Tablet Per Dose

Compare to active Unisom® SleepTabs®



Actual Size



CONVENIENT RECLOSING TAE

32 Tablets

### **GOOD SENSE SLEEP AID**

doxylamine succinate tablet

| <b>Product Information</b> | uct Information |                    |               |  |
|----------------------------|-----------------|--------------------|---------------|--|
| Product Type               | HUMAN OTC DRUG  | Item Code (Source) | NDC:0113-0441 |  |
| 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 |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                    |          |  |
| MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)          |          |  |
| ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J) |          |  |
| DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)  |          |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                       |          |  |

| Product Characteristics |      |              |          |  |
|-------------------------|------|--------------|----------|--|
| Color                   | BLUE | Score        | no score |  |
| Shape                   | OVAL | Size         | 10 mm    |  |
| Flavor                  |      | Imprint Code | L441     |  |
| Contains                |      |              |          |  |

| P | Packaging        |  |                             |                    |
|---|------------------|--|-----------------------------|--------------------|
| # | Item Code        | Package Description                                    | <b>Marketing Start Date</b> | Marketing End Date |
| 1 | NDC:0113-0441-64 | 32 in 1 CARTON   | 04/14/1997                  |                    |
| 1 |                  | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product |                             |                    |
| 2 | NDC:0113-0441-73 | 16 in 1 CARTON   | 08/03/1997                  |                    |
| 2 |                  | 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                               | 04/14/1997           |                    |
|                       |  |                      |                    |

## Labeler - L. Perrigo Company (006013346)

Revised: 7/2020 L. Perrigo Company