WAL SOM NIGHTTIME SLEEP AID- doxylamine succinate tablet Walgreen Company

Walgreen Co. Wal-Som® 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 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 Compare to Unisom® Sleep Tabs® active ingredient NIGHTTIME SLEEP AID Wal-Som® DOXYLAMINE SUCCINATE TABLETS, 25 mg / NIGHTTIME SLEEP AID NIGHTTIME TABLETS Clinically tested, proven effective 48 TABLETS ONE TABLET PER DOSE ACTUAL SIZE



WAL SOM NIGHTTIME SLEEP AID doxylamine succinate tablet **Product Information Product Type** HUMAN OTC DRUG NDC:0363-0441 Item Code (Source) **Route of Administration** ORAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength DOXYLAMINE SUCCINATE 25 mg **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) **Inactive Ingredients Ingredient Name** Strength MAGNESIUM STEARATE (UNII: 70097M6I30) MICROCRYSTALLINE CELLULOSE (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 2 pieces OVAL 10 mm Shape Size Flavor Imprint Code L441 Contains Packaging # Item Code **Package Description** Marketing Start Date Marketing End Date 1 NDC:0363-0441-67 48 in 1 CARTON 03/05/1999 1 in 1 BLISTER PACK; Type 0: Not a Combination Product 1 2 NDC:0363-0441-01 1 in 1 CARTON 09/28/2012 2 96 in 1 BOTTLE; Type 0: Not a Combination Product **Marketing Information** Marketing Category **Application Number or Monograph Citation** Marketing Start Date **Marketing End Date** ANDA ANDA040167 03/05/1999

Labeler - Walgreen Company (008965063)