

**NIGHT TIME SLEEP AID- doxylamine succinate tablet**  
**Advanced Rx LLC**

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**Night Time Sleep Aid**

***Active ingredient (in each tablet)***

Doxylamine succinate 25 mg

***Purpose***

Nighttime sleep-aid

***Use***

- helps to reduce difficulty in falling asleep

***Warnings***

**Ask a doctor before use if you have**

- a breathing problem such as asthma, emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

**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 and over:**take one tablet 30 minutes before going

to bed; take once daily or as directed by a doctor

- **children under 12 years:**do not use

***Other information***

- store at 20°-25°C (68° and 77° F)
- protect from excessive moisture
- DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED.

***Inactive ingredients***

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

***Questions?***

call toll-free **1-800-630-8895**

**Distributed by:**

**ADVANCED RX LLC**

1942 NE 163rd St North Miami Beach,  
FL 33162 U.S.A

\*Compare to the active ingredient in Unisom<sup>®</sup> Sleeptabs<sup>®</sup>

**NDC 80513-371-25**

**Night Time Sleep Aid**

Doxylamine Succinate 25 mg

**225 Tablets**

\*This product is not manufactured or distributed by the owner of the registered trademark Unisom<sup>®</sup> Sleeptabs<sup>®</sup>.

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**PUREGEN LABS**  
 Compare to the active ingredient in Unisom® SleepTabs\*\*  
 NDC 80513-371-25

**NIGHT TIME SLEEP AID**  
 Doxylamine Succinate

**25 MG**

✓ Clinically Tested  
 ✓ Proven Effective

**225 Tablets**

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

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient (in each tablet)</b> Doxylamine succinate 25 mg.....Nighttime sleep-aid	
<b>Uses</b> helps to reduce difficulty in falling asleep	
<b>Warnings</b> <b>Ask a doctor before use if you have</b> <ul style="list-style-type: none"> <li>■ a breathing problem such as asthma,</li> <li>emphysema or chronic bronchitis</li> <li>■ difficulty in urination due to enlargement of the prostate gland</li> <li>■ glaucoma</li> </ul> <b>Ask a doctor or pharmacist before use if you are taking any other drugs.</b> <b>When using this product</b> <ul style="list-style-type: none"> <li>■ avoid alcoholic beverages</li> <li>■ take only at bedtime</li> </ul> <b>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.</b> <b>If pregnant or breast-feeding, ask a health professional before use.</b>	

PEEL FOR DIRECTIONS

LIFT HERE

<b>Drug Facts (continued)</b> 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]
<b>Directions</b> <ul style="list-style-type: none"> <li>■ adults and children 12 years and over: take one tablet 30 minutes before going to bed; take once daily or as directed by a doctor</li> <li>■ children under 12 years: do not use</li> </ul>
<b>Other information</b> <ul style="list-style-type: none"> <li>■ store at 20° - 25°C (68° and 77° F)</li> <li>■ protect from excessive moisture</li> </ul>
<b>Inactive ingredients</b> dicalcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate
<b>Questions?</b> call toll free 1-800-630-8895

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HINGE

**Good Neighbor 44-386**  
**Good Neighbor 44-386**

<b>NIGHT TIME SLEEP AID</b>			
doxylamine succinate tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80513-371
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	25 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)		
	FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)		
	MAGNESIUM STEARATE (UNII: 70097M6130)		
	MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		

**SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)**

### Product Characteristics

<b>Color</b>	blue (light blue)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	44;386
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-371-25	225 in 1 BOTTLE; Type 0: Not a Combination Product	08/29/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040564	08/27/2004	

**Labeler** - Advanced Rx LLC (042795108)

Revised: 2/2025

Advanced Rx LLC