

SLEEP AID- doxylamine succinate tablet
SUPERVALU INC.

Equaline 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

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 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.

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

- **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 1-855-423-2630 Mon-Fri 8 am to 6 pm CST

Principal display panel

EQUALINE®

compare to
Unisom® SleepTabs®
active ingredient*

NDC 41163-986-22

nighttime
sleep aid

doxylamine succinate 25 mg
(nighttime sleep aid)

- *just one tablet per dose*

48 mini tablets

actual size

**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®.
50844 REV1120C38622

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PROVIDENCE, RI 02908 USA

100% *Quality* GUARANTEED

EQUALINE®

nighttime
sleep aid

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EQUALINE®

nighttime
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B-00105-386-22-R
REV11/12/0038622

Do not Print or Varnish
Lot and Exp Date ONLY



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50844 REV11/20/038622

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Other information
■ children under 12 years: do not use
daily or as directed by a doctor
take one tablet 30 minutes before going to bed; take once

Directions ■ adults and children 12 years and over:
Keep out of reach of children. In case of overdose, get
medical help or contact a Poison Control Center right away.

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

Do not use in children under 12 years of age
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Use helps to reduce difficulty in falling asleep
Doxylamine succinate 25 mg..... Nighttime sleep aid
(in each tablet)

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Purpose
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KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Equaline 44-386

SLEEP AID

doxylamine succinate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-986
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
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-986-22	3 in 1 CARTON	06/30/2019	
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	06/30/2019	

Labeler - SUPERVALU INC. (006961411)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(41163-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(41163-986) , pack(41163-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(41163-986)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(41163-986)

Revised: 4/2023

SUPERVALU INC.