SLEEP AID- doxylamine succinate tablet Strategic Sourcing Services, LLC (Health Mart)

Health Mart 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

- take only at bedtime
- avoid alcoholic beverages

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

Principal display panel

Health Mart®

NDC 62011-0401-1

Compare to Unisom® SleepTabs® active ingredient*

Sleep Aid Tablets

Doxylamine Succinate 25 mg Nighttime Sleep Aid

One Tablet Per Dose

Actual Size

32 TABLETS

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 REV1120A38627

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Rev. 06/21



Sleep Aid Tablets



Health Mart.

NDC 62011-0401-1

Compare to Unisom® SleepTabs® active ingredient*

Sleep Aid Tablets

Doxylamine Succinate 25 mg Nighttime Sleep Aid

One Tablet Per Dose





32 TABLETS

B-1241-386-27-RR REV1120A38627

Rev. 06/21 Money Back Guarantee мим. ћеаЙлтаൻ. сот © 2011 McKesson Corporation Memphis, TN 38141 Strategic Sourding Services, LLC Distributed by McKesson Corp., via

medical help or contact a Poison Control Center right Keep out of reach of children. In case of overdose, get before use. If pregnant or breast-feeding, ask a health professional

symptom of a serious underlying medical illness. continuously for more than two weeks. Insomnia may be a Stop use and ask a doctor if sleeplessness persists

- take only at bedtime ■ avoid alcoholic beverages
- When using this product

Ask a doctor or pharmacist before use if you are taking

- djøuq djøncomø
- qitticulty in urination due to enlargement of the prostate chronic bronchitis
 - a breathing problem such as asthma, emphysema or Ask a doctor before use if you have

Do not use in children under 12 years of age

helps to reduce difficulty in falling asleep

bis-qeals amithtgiM... Doxylamine succinate 25 mg.... Active ingredient (in each tablet) Purpose Drug Facts

Inc., owner of the registered trademark Unisom® SleepTabs®. 50844 REV1120A38627 This product is not manufactured or distributed by Chattem,

8:30 AM-4:00 PM ET, Monday-Friday

GINESTIONS OF COMMENTS? Call 1-800-426-9391

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

- see end flap for expiration date and lot number ■ store at controlled room temperature 20°-25°C (68°-77°F)
- OPENED OR BLISTER IS TORN OR BROKEN ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS Uther information
 - children under 12 years: do not use directed by a doctor
- minutes before going to bed; take once daily or as adults and children 12 years and over: take one tablet 30 Directions

Drug Facts (continued)

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

BROKEN OR SHOWS ANY SIGNS OF TAMPERING

no print / no varnish area

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN,

Health Mart 44-386

SLEEP AID

doxylamine succinate tablet

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0401
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Stronath
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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				

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:62011- 0401-1	2 in 1 CARTON	05/20/2019	08/09/2024
	L	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	05/20/2019	08/09/2024	

Labeler - Strategic Sourcing Services, LLC (Health Mart) (116956644)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(62011-0401)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(62011-0401), pack(62011-0401)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(62011-0401)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(62011-0401)

Revised: 12/2023 Strategic Sourcing Services, LLC (Health Mart)