NIGHTTIME SLEEP AID- diphenhydramine hcl tablet, film coated Strategic Sourcing Services, LLC (Health Mart)

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Health Mart 44-367

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Use

for relief of occasional sleeplessness

Warnings

Do not use

- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- a breathing problem such as 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 sedatives or tranquilizers.

When using this product

- use caution when driving a motor vehicle or operating machinery
- drowsiness will occur
- avoid alcoholic beverages

Stop use and ask a doctor if

sleeplessness persists continuously for more than 2 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 (1-800-222-1222) right away.

Directions

- do not take more than directed
- adults and children 12 years and over: take 2 caplets at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

Other information

- each caplet contains: calcium 30 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- protect from moisture
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, dicalcium phosphate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silica gel, stearic acid, talc, titanium dioxide

Questions or comments?

Call 1-800-426-9391

Principal display panel

Health Mart®

NDC 62011-0343-1

*Compare to Simply Sleep® active ingredient

Nighttime Sleep Aid

Diphenhydramine HCl 25 mg

Nighttime Sleep-Aid

Helps You Fall Asleep

Does NOT Contain Pain Reliever • Non-Habit Forming

Actual Size

24Caplets

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 McNeil Consumer Healthcare, owner of the registered trademark Simply Sleep®. 50844 REV0516A36708

McKESSON

Another Quality Product Distributed by McKesson One Post Street, San Francisco, CA 94104 Money Back Guarantee healthmart.com

Nighttime Sleep Aid

NDC 62011-0343-1

*Compare to Simply Sleep® active ingredient

Nighttime Sleep Aid

Health Mart.

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Nighttime Sleep Aid

Diphenhydramine HCl 25 mg Nighttime Sleep-Aid

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24 Caplets

теаптап.сот Money Back Guarantee One Post Street, San Francisco, CA 94104 Distributed by McKesson Another Quality Product

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80735A3150V3R 50844 trademark Simply Sleep®.

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USB for relief of occasional sleeplessness

Diphenhydramine HCI 25 mg Active ingredient (in each caplet) Purpose

B-1241-367-08-R REV0516A36708

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

no print / no varnish area lot no & exp. date

McNeil Consumer Healthcare, owner of the registered This product is not manufactured or distributed by

Questions or comments? Call 1-800-426-9391

Inactive ingredients com starch, dicalcium

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- store at 25°C (77°F); excursions permitted between

 - esch caplet contains: calcium 30 mg

44-367

NIGHTTIME SLEEP AID

diphenhydramine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62011-0343
Route of Administration	ORAL		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg			

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C BLUE NO. 1ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics					
Color	BLUE	Score	no score		
Shape	OVAL	Size	11mm		
Flavor		Imprint Code	44;367		
Contains					

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:62011-0343-1	2 in 1 CARTON	06/10/2000				
1		12 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		
OTC MONOGRAPH FINAL	part338	06/10/2000			

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

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		038154464	PACK(62011-0343)		

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(62011-0343)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(62011-0343), PACK(62011-0343)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(62011-0343)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(62011-0343)

Revised: 3/2020 Strategic Sourcing Services, LLC (Health Mart)