# SLEEP AID- diphenhydramine hcl tablet, film coated Topco Associates, LLC

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**TopCare 44-672** 

#### Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

### **Purpose**

Nighttime sleep-aid

#### Uses

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

#### Warnings

#### Do not use

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

### Ask a doctor before use if you have

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

### Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

### When using this product

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 right away.

#### **Directions**

- do not take more than directed
- adults and children 12 years and over: take 2 caplets (50 mg) at bedtime if needed, or as directed by a doctor
- children under 12 years: do not use

#### Other information

- each caplet contains: calcium 65 mg
- avoid excessive heat (greater than 100°F) or humidity
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

#### Inactive ingredients

corn starch, D&C red #27 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, talc, titanium dioxide

#### **Questions or comments?**

1-888-423-0139

#### Principal display panel

**TopCare**®

health

NDC 36800-672-06

COMPARE TO VICKS® ZzzQUIL® ACTIVE INGREDIENT\*

NIGHTTIME Sleep Aid

DIPHENHYDRAMINE HCl, 25 mg

#### **NIGHTTIME SLEEP AID**

- Non-Habit Forming
- Not for Treating Pain, Cold or Flu

**200** CAPLETS

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007 ©TOPCO LNKA0521 QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

Visit here for more information:

http://topbrnds.com/48ZZY7

#### **√ QUALITY GUARANTEED**

\*This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark VICKS® ZzzQuil<sup>®</sup>.

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**Top Care 44-672** 

#### SLEEP AID

diphenhydramine hcl tablet, film coated

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-672
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg		

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	purple	Score	no score
Shape	OVAL	Size	14mm
Flavor		Imprint Code	44;672
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:36800-672-	200 in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2015	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M010	07/24/2015		

## Labeler - Topco Associates, LLC (006935977)

### **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(36800-672)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(36800-672)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(36800-672)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(36800-672)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(36800-672)

Revised: 6/2024 Topco Associates, LLC