

NIGHTTIME SLEEP AID- diphenhydramine hcl tablet, film coated

WinCo Foods, LLC

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.

Winco 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
- 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

- 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
- 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?

Call **800-824-1706** Monday - Friday 9am-4pm MST

Principal Display Panel

*Compare to the active ingredient in SIMPLY SLEEP®

Safe, Non-Habit Forming

Does NOT Contain

Pain Reliever

WinCo®

FOODS

NIGHTTIME

Sleep Aid

DIPHENHYDRAMINE HCl 25 mg/

SLEEP-AID

100

Caplets

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

The Supermarket Low Price Leader®

100% SATISFACTION GUARANTEE

Comments & Questions?

800-824-1706 • www.wincofoods.com

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

*This product is not manufactured or distributed
by MCNEIL CONSUMER HEALTHCARE, distributor
of SIMPLY SLEEP®.

50844 REV0516A36712 WF1612



NIGHTTIME SLEEP AID

diphenhydramine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-115
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

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:67091-115-10	1 in 1 CARTON	06/10/2000	
1		100 in 1 BOTTLE; 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 - WinCo Foods, LLC (056098817)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(67091-115)

Establishment			
Name	Address	ID/FEI	Business Operations

LNK International, Inc.		832867894	MANUFACTURE(67091-115)
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Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(67091-115) , PACK(67091-115)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(67091-115)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(67091-115)