

NIGHTTIME SLEEP AID- diphenhydramine hcl tablet, film coated
CVS Pharmacy

CVS 44-367

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

- for 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

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 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, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

♥CVS Health®

Compare to the active ingredient in Simply Sleep®*

Mini-Caplets**Nighttime Sleep-Aid****DIPHENHYDRAMINE HCl, 25 mg Nighttime Sleep-Aid**

Helps to reduce difficulty in falling asleep

Does not contain pain reliever

Actual Size

Package Contains One Bottle

225 MINI-CAPLETS

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY

SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Simply Sleep®.

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One CVS Drive, Woonsocket, RI 02895

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CVS 44-367

NIGHTTIME SLEEP AID

diphenhydramine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-367
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)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:59779-367-08	2 in 1 CARTON	06/10/2000	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59779-367-22	4 in 1 CARTON	06/10/2000	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:59779-367-12	1 in 1 CARTON	06/10/2000	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:59779-367-51	365 in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2000	
5	NDC:59779-367-20	1 in 1 CARTON	06/10/2000	
5		225 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	06/10/2000	

Labeler - CVS Pharmacy (062312574)**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(59779-367)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(59779-367) , pack(59779-367)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(59779-367)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(59779-367)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(59779-367)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(59779-367)