

## **SLEEP AID NIGHTTIME- diphenhydramine hcl tablet, film coated**

**Walgreen Company**

*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.*

-----

**Walgreens 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
- **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, 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******Walgreens***

*Compare to Simply Sleep<sup>®</sup> active ingredient<sup>††</sup>*

**NDC 0363-0367-08**

**Sleep Aid**

DIPHENHYDRAMINE HCl 25 mg / NIGHTTIME SLEEP AID

NIGHTTIME      MINI CAPLETS

- For a restful night's sleep
- Does not contain pain reliever
- Non-habit forming

**24 MINI-CAPLETS**

ACTUAL SIZE

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

PHARMACIST ***Walgreens*** RECOMMENDED<sup>†</sup>

Walgreens Pharmacist Survey

<sup>††</sup>This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Simply Sleep<sup>®</sup>.

50844    REV1019A36708

**DISTRIBUTED BY: WALGREEN CO.**

200 WILMOT RD., DEERFIELD, IL 60015

***Walgreens***

**100% SATISFACTION**

**GUARANTEED**

walgreens.com ©2018 Walgreen Co.

DISTRIBUTED BY: WALGREEN CO.  
200 WILMOT RD., DEERFIELD, IL 60015  
walgreens.com ©2018 Walgreen Co.

**100% SATISFACTION**  
*Walgreens*  
**GUARANTEED**

ITEM 609984 W00000-0000-0  
1191704460  
6

ORG0818-F  
REV0120

Lot & Exp are EMBOSSED  
NOT ink Jetted

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

50844 REV1019A36708

**Drug Facts**

**KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

**Active ingredient (in each caplet)**  
Diphenhydramine HCl 25 mg ..... Nighttime sleep-aid

**Purpose**  
■ 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  
■ 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  
■ 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, 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

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



Walgreens

Walgreens

Compare to Simply Sleep® active ingredient††

NDC 0363-0367-08

# Sleep Aid

DIPHENHYDRAMINE HCl 25 mg / NIGHTTIME SLEEP AID

**NIGHTTIME** **MINI CAPLETS**

- For a restful night's sleep
- Does not contain pain reliever
- Non-habit forming

B-2201-367-08-H  
REV1019A36708

24 MINI CAPLETS



ACTUAL SIZE

Walgreens 44-367

**SLEEP AID NIGHTTIME**

diphenhydramine hcl tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0367
<b>Route of Administration</b>	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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

**Product Characteristics**

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	44;367
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0367-08	2 in 1 CARTON	06/10/2000	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-0367-91	1 in 1 CARTON	06/10/2000	10/02/2021

2		125 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0363-0367-13	1 in 1 CARTON	06/10/2000	
3		250 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0363-0367-12	1 in 1 CARTON	06/10/2000	
4		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** - Walgreen Company (008965063)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0367)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0367)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(0363-0367) , PACK(0363-0367)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0363-0367)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(0363-0367)

Revised: 1/2020

Walgreen Company