

SLEEP AID DYE-FREE 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 44-627

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

- glaucoma
- 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

- drowsiness will occur
- avoid alcoholic beverages
- do not drive a motor vehicle or operate machinery

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 28 mg
- 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, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc

Questions or comments?

1-800-426-9391

Principal Display Panel

Well at

Walgreens

WALGREENS PHARMACIST RECOMMENDED[□]

NDC 0363-0627-12

DYE-FREE • NIGHTTIME

Sleep Aid

**Diphenhydramine HCl 25 mg /
Nighttime Sleep Aid**

- For a restful night's sleep
- Does not contain pain reliever
- Safe, non-habit forming

100

MINI-CAPLETS

Actual Size

DYE-FREE

NIGHTTIME

**Compare to Simply Sleep[®]
active ingredient^{‡‡}**

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

[□]Walgreens Pharmacist Survey Study,
November 2014.

^{‡‡}This product is not manufactured
or distributed by McNeil Consumer
Healthcare, owner of the registered
trademark Simply Sleep[®].

50844 REV0915A62712

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ORIG0513-F_R01

Drug Facts (continued)
Questions or comments?
 1-800-426-9891

*Walgreens Pharmacist Survey Study, November 2014.
 ††This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Simply Sleep®.
 50844 REV0915A62712

ITEM 280726 W10058-0516-L
 TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

6
 B-2201-627-12-R
 REV0915A62712

Drug Facts (continued)
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.

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 B-2201-627-12-R
 REV0915A62712

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts
Active ingredient (in each caplet)
 Diphenhydramine HCl 25 mg Nighttime sleep-aid

Use for relief of occasional sleeplessness


Warnings
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 ■ 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**
 ■ glaucoma
 ■ 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
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 ■ do not drive a motor vehicle or operate machinery

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DYE-FREE • NIGHTTIME
Sleep Aid
 Diphenhydramine HCl 25 mg / Nighttime Sleep Aid
 • For a restful night's sleep.
 • Does not contain pain reliever
 • Safe, non-habit forming


100
 MINI-CAPLETS

Actual Size 

Well at Walgreens

WALGREENS PHARMACIST RECOMMENDED!

DYE FREE 

NIGHTTIME 

Compare to Simply Sleep® active ingredient††

NDC 0363-0627-12

Walgreens 44-627

SLEEP AID DYE-FREE NIGHTTIME

diphenhydramine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0627
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)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	44;627
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0627-12	1 in 1 CARTON	07/01/2013	
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	07/01/2013	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0627)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0627)

Revised: 5/2017

Walgreen Company