

SLEEP AID NIGHTTIME- diphenhydramine hcl capsule

CVS Pharmacy

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.

Drug Facts

Active ingredient (in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep-aid

Uses

For relief of occasional sleeplessness.

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

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

avoid alcoholic drinks

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. (1-800-222-1222)

Directions

- adults and children 12 years of age and older: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- store between 15-30°C (59-86°F)

Inactive ingredients

edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, propylene glycol*, purified water, sorbitol-sorbitan

*contain one or more of these ingredient

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in Unisom® SleepGels®*†

MAXIMUM STRENGTH

Nighttime**Sleep Aid**

DIPHENHYDRAMINE HCl, 50 mg

Nighttime Sleep-Aid

Safe, non-habit forming

SOFTGELS

(One Softgel Per Dose)

**This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepGels®.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

Product Label

Drug Facts

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Diphenhydramine HCl 50 mg

Purpose
Nighttime Sleep Aid

Use For relief of occasional sleeplessness.

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Directions

■ adults and children 12 years of age and over: 1 softgel (50 mg) at bedtime if needed, or as directed by a doctor

Other information ■ store between 15-30°C (59-86°F)

Inactive ingredients: edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol*, sorbitol
*contains one or more of these ingredients

Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

This product is not manufactured or distributed by Chattem, Inc., distributor of Unisom® SleepGels®.

Package Contains One Bottle

Actual Size

Compare to the active ingredient in Unisom® SleepGels®†

Softgels

NDC 69842-734-64

MAXIMUM STRENGTH

Nighttime

Sleep Aid

DIPHENHYDRAMINE HCl, 50 mg

Nighttime sleep aid

Safe, non-habit forming

Actual Bottle Size on Side panel

1 Bottle

64 SOFTGELS

(One Softgel Per Dose)

Actual Size

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

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Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895
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CVS Quality
Money Back Guarantee

PLD-G270
FD005234

Lot No.:
Exp. Date:

871292

0 50428 27579 5

PLEASE RECYCLE

CVS HEALTH Maximum Strength Nighttime Sleep Aid

SLEEP AID NIGHTTIME

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-734
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	13mm
Flavor		Imprint Code	P50;A99;D50;AP018
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-734-64	1 in 1 BOX	12/31/2018	
1		64 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:69842-734-32	1 in 1 BOX	12/31/2018	
2		32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:69842-734-96	96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	12/31/2018	

Labeler - CVS Pharmacy (062312574)

Revised: 1/2019

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