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®.

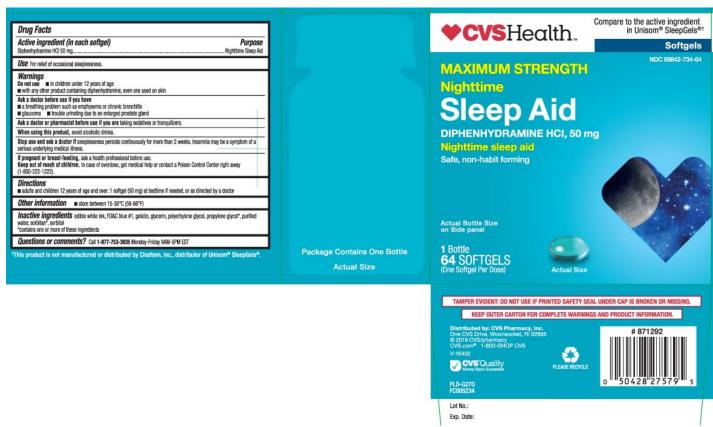
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

Product Label



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			

l	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
	$ \begin{tabular}{ll} \textbf{DIPHENHYDRAMINE HYDRO CHLO RIDE} & (UNII: TC2D6 JAD40) & (DIPHENHYDRAMINE -UNII: 8GTS82S83M) \\ \end{tabular} $	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg	

Inactive Ingredients		
Strength		

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

P	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 CVS Pharmacy