

DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule
CVS Pharmacy, Inc.

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.

5347-CVS

Drug Facts

Active Ingredient (in each mini-capsule)

Diphenhydramine HCl 25mg

Purpose

Nighttime sleep-aid

Uses

for relief of occasional sleeplessness

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 Poison Control Center (1-800-222-1222) right away.

Directions

- **Adults and children 12 years and over:** take 2 mini-capsules (50mg) at bedtime if needed, or as directed by a doctor

Other Information

- Store at 25°C(77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number
- protect from moisture

citric acid, edible ink, FD&C blue #1, FD&C red #3, FD&C red #40, gelatin, lactose, polysorbate 80, potassium sorbate, starch, titanium dioxide

Question or comments?

1-800-231-4670

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

BAND AROUND CAPSULE IS BROKEN OR MISSING

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Distributed by: CVS Pharmacy, Inc.

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CVSHealth

Compare to the active ingredient in Unisom® SleepMinis™*

Nighttime Sleep-Aid

Diphenhydramine HCl, 25mg

Nighttime sleep-aid

Non-habit forming

60 Mini-Capsules





DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-537
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		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
GELATIN (UNII: 2G86QN327L)				
STARCH, CORN (UNII: O8232NY3SJ)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	14mm	
Flavor		Imprint Code	5347	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-537-11	1 in 1 CARTON	06/22/2018	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-537-51	365 in 1 BOTTLE; Type 0: Not a Combination Product	06/22/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part338	06/22/2018		

Labeler - CVS Pharmacy, Inc. (062312574)

Revised: 4/2020

CVS Pharmacy, Inc.