

**MAXIMUM STRENGTH NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled**  
**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.*

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**MAXIMUM STRENGTH Nighttime Sleep-Aid**

**Drug Facts**

**Active ingredient (in each softgel)**

Diphenhydramine HCl 50 mg

**Purpose**

Nighttime sleep-aid

**Use**

- 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**

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

**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 persist continuously for more than 2 weeks. Insomnia may be a symptom of 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**

- 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 at room temperature 15°-30°C (59°-86°F) and avoid excessive heat
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

FD&C blue #1, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol, titanium dioxide

Questions or comments?

Call toll free: 1-888-333-9792

PRINCIPAL DISPLAY PANEL

MAXIMUM STRENGTH Nighttime Sleep-Aid

200 SOFTGELS

\*Compare to the active ingredient in Unisom® SleepGels® Nighttime Sleep-Aid



MAXIMUM STRENGTH NIGHTTIME SLEEP AID			
diphenhydramine hydrochloride capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-624
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 400 (UNII: B697894SGQ)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Product Characteristics				
Color	blue (clear)	Score	no score	
Shape	CAPSULE (oval)	Size	14mm	
Flavor		Imprint Code	206	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-624-02	200 in 1 BOTTLE; Type 0: Not a Combination Product	02/11/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part338		02/11/2020	

**Labeler** - CVS PHARMACY, INC. (062312574)

**Registrant** - Spirit Pharmaceuticals LLC (179621011)

## Establishment

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LIMITED		677385498	manufacture(69842-624)

Revised: 12/2020

CVS PHARMACY, INC.