# NIGHTTIME SLEEP AID- diphenhydramine hydrochloride capsule, liquid filled SPIRIT PHARMACEUTICALS LLC

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#### **NIGHTTIME SLEEP-AID**

**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

- 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. 1(800)222-1222

#### **Directions**

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

## Inactive ingredients

FD&C Blue#1, gelatin, glycerin, polyethylene glycol-400, propylene glycol, sorbitol, titanium dioxide, water

### Questions or comments?

1-888-333-9792

#### PRINCIPAL DISPLAY PANEL

Maximum Strength

Nighttime Sleep-aid

Diphenhydramine HCl 50 mg - Nighttime Sleep-Aid

Helps reduce difficulty falling asleep Non-habit forming

8 Softgels



## **NIGHTTIME SLEEP AID**

diphenhydramine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4147
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (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)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SORBITOL (UNII: 506T60A25R)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	206;903	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68210- 4147-8	1 in 1 CARTON	04/28/2021		
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	04/28/2021	

## Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

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