# NIGHTTIME SLEEP AID- diphenhydramine hydrochloride tablet SPIRIT PHARMACEUTICALS LLC

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#### **NIGHTTIME SLEEP AID CAPLETS**

**Drug Facts** 

### Active ingredients (in each caplet)

Diphenhydramine HCl 25mg

### **Purpose**

nighttime sleep-aid

#### Uses

for the 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
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

# Stop use and ask a doctor if

sleeplessness persists 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.

# **Overdose warning**

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 and take 2 caplets at bedtime if needed, or as directed by over

children under 12 years do not use

#### Other information

each caplet contains: calcium 25 mg

store between 20-25°C(68-77°F). Avoid high humidity. Protect from light.

### Inactive ingredients

Colloidal siicon dioxide, croscarmellose sodium, dicalcium phosphate, FD&C Blue#1, FD&C Blue#2, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

### Questions or comments?

1-888-333-9792

#### PRINCIPLA DISPLAY PANEL

Nighttime sleep-aid Diphenhydramine HCI 25 mg - Nighttime Sleep-Aid

Does NOT contain pain reliever

Non-habit forming

36 Caplets



### **NIGHTTIME SLEEP AID**

diphenhydramine hydrochloride tablet

## **Product Information**

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

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Ingredient Name	<b>Basis of Strength</b>	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	S5
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210- 4132-3	1 in 1 CARTON	04/28/2021	
1		36 in 1 BOTTLE; Type 0: Not a Combination Product		

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Marketing	Information
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Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M010	04/28/2021	

# Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Revised: 12/2023 SPIRIT PHARMACEUTICALS LLC